Exhibit 109

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	Civil Action No. 3:16-md-2738-MAS-RLS

EXPERT REPORT*
DAVID A. KESSLER, M.D.

Submitted November 15, 2023

* This Amended Report should substitute for my 2018 report.

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SCHEDULE[1]

APPENDICES

[1] The schedules were prepared by legal staff at my direction and under my review.

I. QUALIFICATIONS AND INTRODUCTION

1. My name is David A. Kessler, M.D. I received my M.D. degree from Harvard Medical School in 1979 and my J.D. degree from the University of Chicago Law School in 1978.

2. I did my pediatrics training at Johns Hopkins Hospital.

3. In 1990, I was appointed by President George H. W. Bush as Commissioner of the United States Food and Drug Administration ("Commissioner") and was confirmed by the United States Senate. I also served in that position under President William Jefferson Clinton until February 1997.

4. I am currently professor of Pediatrics and Epidemiology, and Biostatistics at University of California, San Francisco.

5. From January 20, 2021-January 19, 2023, I served as Chief Science Officer of the United States Covid-19 Response and co-led what was known as Operation Warp Speed (subsequently known as the Counter Measures Acceleration Group (CAG)).

6. I have taught food and drug law at Columbia University Law School, and I have testified many times before the United States Congress on food, drug, and consumer protection issues under federal and state law. Over the last thirty years, I have published numerous articles in legal, medical, and scientific journals on the federal regulation of food, drugs, and medical devices. I have had special training in pharmacoepidemiology at Johns Hopkins Hospital.

7. My resume is attached as Appendix A. A list of cases in which I have testified as an expert witness in the last ten years, and documentation of my expert witness fee, is attached as Appendix B.

8. As Commissioner, I had ultimate responsibility for implementing and enforcing the United States Food, Drug, and Cosmetic Act (the "Act"). I was responsible for overseeing five

Centers within the FDA. They included, among others, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Center for Food Safety and Applied Nutrition which regulated cosmetics, and the Center for Biologics Evaluation and Research. In addition to those duties, I placed high priority on getting promising therapies for serious and life-threatening diseases to patients as quickly as possible. During my tenure as Commissioner, the FDA announced a number of new programs including: the regulation of the marketing and sale of tobacco products to children; nutrition labeling for food; user fees for drugs and biologics; preventive controls to improve food safety; measures to strengthen the nation's blood supply; and the MEDWatch program for reporting adverse events and product problems. I created an Office of Criminal Investigation within the Agency to investigate suspected criminal violations of the Act, FDA regulations and other related laws. While I was Commissioner, I attempted to institute a voluntary reporting system of adverse events from cosmetics. The cosmetic industry, through its association, vigorously opposed such regulation.

9. Over the past forty years, I have published numerous articles in legal, medical, and scientific journals on the FDA federal regulation.

10. I have served as senior advisor to TPG Capital, a leading global private equity firm, which owns pharmaceutical and biomedical companies. I served on the board of Aptalis Pharma, Stoke Pharmaceuticals, Tokai Pharmaceuticals and the medical device and biologics company Immucor, Inc. In these advisory and fiduciary capacities, I have advised companies on the standards and duties of care within the pharmaceutical and medical device industry. I also chaired the compliance committee of Aptalis Pharma, and currently chair the quality committee at Immucor, Inc., which involves ensuring compliance with the FDA's regulations and requirements.

11. I have served as a consultant/staff to the United States Senate Labor and Human Resources Committee and was responsible for, among other things, FDA issues.

12. I have had access to 1) MDL discovery repository; 2) deposition transcripts and exhibits; 3) trial testimony and exhibits; 4) all of the documents available on Johnson & Johnson's (JNJ) website Review the Evidence page of https://www.factsabouttalc.com;[2] 5) FDA's website.

13. The documents I have considered are listed in Appendix C.

14. At my request, and subject to my directions and review, the attached Schedules were prepared by legal staff.

15. Based on my review of the documents listed in Appendix C, and utilizing methods I have used while at FDA, academia, and on boards of corporate entities, including my training and experience, I have a number of opinions that are detailed below.

16. It is my understanding that the cases in this litigation include, but are not limited to, the following claims[3] as they relate to talcum powder products:

a. Negligence;

b. Negligent Misrepresentation;

c. Strict Products Liability – Failure to Warn;

d. Strict Product Liability – Defective Manufacture and Design;

e. Breach of Express Warranties;

f. Breach of Implied Warranty of Merchantability;

g. Breach of Implied Warranty of Fitness for a Particular Purpose;

h. Fraud;

[2] https://jjcloud.ent.box.com/s/2x692lcj24crvjunf0lnu590zw5g528e

[3] It is my understanding that a Motion to Amend the Complaint is currently pending. Should the Court amend the Complaint as proposed, this will not affect my opinions within this report.

i. Fraudulent Concealment;

j. Violation of Consumer Protection Laws;

k. Civil Conspiracy;

l. Loss of Consortium;

m. Punitive Damages;

n. Discovery Rule and Tolling;

o. Wrongful Death;

p. Survival Action.[4]

17. It is my understanding the Defendants in this case are Johnson & Johnson; Johnson & Johnson Consumer Inc. f/k/a Johnson & Johnson Consumer Companies, Inc.; Imerys Talc America, Inc., f/k/a Luzenac, Inc., f/k/a Rio Tinto Materials, Inc.; and Personal Care Products Council ("PCPC") f/k/a Cosmetic, Toiletry, and Fragrance Association ("CTFA"). Use of any individual Defendant name is meant to reflect the totality of Defendants.

18. It is my understanding that the products at issue in this matter include JNJ's talcum powder products, including Johnson's Baby Powder and Shower to Shower.

19. It is my understanding that the talc that went into these products was mined at[5]:

1946-1964	Val Chisone, IT	2000-2001	Argonaut Rainbow Hamm (Windham)
1964-1966	Hammondsville, VT Val Chisone, IT	2001-2003	Argonaut
1966-1979	Hammondsville	2003-2009	Zhizhua quarry Guping quarry Huamei mine Shang Lang quarry Tongzi quarry

[4] See Plaintiffs First Amended Master Long Form Complaint and Jury Demand for MDL 3:16-md-2738-FLW-LHG, Dkt. 132 filed March 16, 2017.

[5] See Defendants Johnson & Johnson Consumer, Inc. and JNJ's Responses to Plaintiffs' Supplemental Interrogatories and Requests for Production of Documents Dated November 10, 2017, at 12-13.

1980	Hammondsville Val Chisone, IT	2009-2010	Zhizhua quarry
1981-1988	Hammondsville	2010	Argonaut
1989-1990	Hammondsville Argonaut Rainbow	2010-Present	Zhizhua quarry
1990-2000	Hammondsville Argonaut Rainbow Hamm (Windham)		

20. The plaintiffs in this case consist of all current plaintiffs in or subsequently added to MDL No. 3:16-md-2738-FLW-LHG. It is my understanding that the plaintiffs in this litigation have been diagnosed with various forms of ovarian cancer, including ovarian cancer, cancer of the fallopian tube, and primary peritoneal cancer.[6]

21. Talcum powder products can be regulated as either drugs or cosmetics depending on their intended use and the claims that are made for the product. Talc may also be used as an inactive ingredient in a number of regulated products. It has also had certain historical uses as a food and color additive and in medical devices. It is my understanding that the products at issue in this matter have been regulated as cosmetic.

22. My opinions in this case focus on the responsibilities of cosmetic manufacturers, focusing on the regulatory interface between cosmetic manufacturers and the FDA, as well as industry standards. I have not been asked to opine on causation issues. I have been asked to address the duties and conduct of defendant cosmetic companies in the face of a potential health hazard. In formulating my regulatory and safety opinions in this case, reviews of the epidemiology, laboratory testing methodology, chemical and geological relationship between talc

[6] *See* Plaintiffs First Amended Master Long Form Complaint and Jury Demand for MDL 3:16-md-2738-FLW-LHG, Dkt. 132 filed March 16, 2017.

and asbestos, health consequences with asbestos and elongated mineral particles, and product formulation and manufacturing were performed. The approach and methods utilized here are consistent with those I have taken to address regulatory questions in academia, my work as a government official, and as a board member advising corporate entities for over forty years.

23. The following is a general timeframe of events:

23.1. In 1894, Johnson & Johnson first marketed talcum powder products.[7]

23.2. In the 1930's, scientists began exploring the geological formation and relationship between asbestos and talc. [8]

23.3. By the mid-1950's, asbestos was recognized as a human carcinogen. Over the next two decades, it was generally agreed that there was no known safe level of asbestos exposure.[9]

23.4. In the early 1960's, inert particles were shown to be capable of ascending through the open human female reproductive tract to the ovaries and peritoneal cavity.[10]

23.5. By the early 1970's, concern was expressed about the presence of asbestos and other fibers in talc. Laboratory tests began to report asbestos fibers in talc products. Asbestos was identified in human lung tissue. Shortly thereafter, talc was identified in human ovarian tissue.[11]

23.6. By the early 1980's, the first epidemiological study demonstrated an association between perineal talcum powder use and ovarian cancer.[12]

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[7] https://ourstory.jnj.com/ accessed 11/14/2023.
[8] Bain, G.W. 1934, Serpentinization, origin of certain asbestos, talc and soapstone depositions. Economic Geology v. 29, no. 4, 397-400.
[9] Doll R. 1955a. Mortality from lung cancer in asbestos workers. Br J Ind Med 12: 81-86.
[10] Egli & Newton. 1961. "The Transport of Carbon Particles in the Human Female Reproductive Tract." Fertility and Sterility 12 (April): 151-55.
[11] *See* Section IV. of this report. Henderson, et al. *A replication technique for the identification of asbestos fibres in mesotheliomas*. Eur J Cancer (1969) DEC;5(6:621); Henderson, et al. *Talc and Carcinoma of the Ovary and Cervix*. The Journal of Obstetrics and Gynecology of the British Commonwealth March 1971 Vol. 78. Pp. 266-272.
[12] Cramer et al. Ovarian cancer and talc: a case-control study. Cancer 1982; 50:372-6.

23.7. Over the next four decades, additional epidemiological studies were performed, continuing to raise concerns about an association between talc and ovarian cancer.[13]

23.8. In 2010, IARC published findings that talc not containing asbestiform fibers was a Group 2B possible human carcinogen. In 2012, IARC confirmed all six forms of asbestos, including fibrous talc (i.e., talc containing asbestiform fibers), as Group 1 known human carcinogens.[14]

23.9. In 2019, FDA found asbestos and fibrous talc in a bottle of Johnson's Baby Powder. That resulted in a lot recall.[15]

23.10. In 2020, Johnson & Johnson discontinued North American sales of talcum powder products. In 2023, Johnson & Johnson stopped the global sale of talcum powder products.[16]

24. Based on my recollection, I was not substantially involved in talc cosmetic matters while I was Commissioner.

25. On November 16, 2018, I submitted an opening expert report. Since that time, and after leaving government service in January 2023, I have had the opportunity to review more documents discussed above. For convenience, I now submit this report which includes my cumulative opinions. Formally, this amended report should substitute for my 2018 report.

[13] *See* Section V. of this report.
[14] IARC Working Group on the Evaluation of Carcinogenic Risks to Humans. "Carbon Black, Titanium Dioxide, and Talc." IARC Monographs on the Evaluation of Carcinogenic Risks to Humans/World Health Organization, International Agency for Research on Cancer 93 (2010): 1-413; IARC Monographs of the Evaluation of Carcinogenic Risks to Humans: Volume 100C," 2012.
[15] https://www.fda.gov/news-events/press-announcements/baby-powder-manufacturer-voluntarily-recalls-products-asbestos
[16] https://www.jnj.com/our-company/johnson-johnson-consumer-health-announces-discontinuation-of-talc-based-johnsons-baby-powder-in-u-s-and-canada.

II. COSMETIC MANUFACTURERS HAVE A RESPONSIBILITY TO SUBSTANTIATE THE SAFETY OF THEIR PRODUCTS PRIOR TO MARKETING

A. The regulatory standards for cosmetics

III. Unlike drugs, the Federal Food, Drug, and Cosmetic Act does not require the premarket approval of cosmetics.

27. FDA promulgated regulations on March 3, 1975, which remain in effect today that require that, "[e]ach ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing." 21 CFR §740.10.

28. The regulations further state that, "[a]ny such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous, statement on the principal display panel: Warning-The safety of this product has not been determined." 21 CFR §740.10.

29. A manufacturer who has not adequately substantiated the safety of their cosmetic product or their ingredients and has not displayed the appropriate warning as noted above cannot ship their product in interstate commerce and would be considered misbranded under the Act. 21 USC §331(a).

30. In reality, most cosmetic manufacturers who are selling a product for which they could not substantiate the safety would likely not choose to put the "Warning-The safety of this product has not been determined" on the product and would attempt to reformulate or remove the product from the market.

31. In addition, a manufacturer of a cosmetic product must assure that the cosmetic's label "shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." 21 CFR §740.10.

32. The regulations also state that, "[a]n ingredient or product having a history of use in or as a cosmetic may at any time have its safety brought into question by new information that in itself is not conclusive. The warning required by paragraph (a) of this section is not required for such an ingredient or product If: (1) The safety of the ingredient or product had been adequately substantiated prior to development of the new information; (2) The new information does not demonstrate a hazard to human health; and (3) Adequate studies are being conducted to determine expeditiously the safety of the ingredient or product."[17] 21 CFR §740.10(b) [emphasis added].

33. A cosmetic is adulterated if it bears or contains, "any poisonous or deleterious substance which may render it injurious to users." 21 USC §361.

34. In my opinion, of all the products that fall under FDA's jurisdiction, cosmetics are among the least regulated. This is reflected in the fact that there is no premarket approval of cosmetic products.

35. Moreover, only very limited resources have ever been committed to cosmetic product review, monitoring, or safety.

36. The limited oversight of cosmetics products has been recognized.

37. In 1978, the United States General Accounting Office (GAO) "concluded that the effectiveness of FLN'S regulatory actions was limited by inadequacies in both FDA'S legislative authority and the industry's participation."[18]

38. In March 1990, the GAO reported to the Subcommittee on Regulation, Business

[17] The regulation continues, this requirement ". . . does not constitute an exemption to the adulteration provisions of the act or to any other requirement in the act or this chapter." 21 USC 740.10(c).
[18] Cosmetics Regulation. Information on Voluntary Actions Agreed to by FDA and the Industry. (GAO/HRD-90-58, Mar. 1990), citing Lack of Authority Hampers Attempts to Increase Cosmetic Safety. (GAO/HRD-78-139, Aug. 1978).

Opportunities, and Energy that the "FDA's regulatory authority over the cosmetics industry is less comprehensive than its authority over food and drugs. Consequently, in its oversight of the cosmetics industry, FDA must rely, in part, on voluntary industry cooperation . . . FDA does not have authority to require the industry to do safety testing and injury reports. FDA must rely on manufacturers to volunteer the data and reports. FDA officials have found that many manufacturers lack adequate data on safety tests and have generally refused to disclose the results of these tests . . . Finally, FDA has been studying the industry report on toxic chemicals used in cosmetics, but has committed no resources to do its own safety reviews and ranking."[6]

39. In their 2017 article, Robert Califf, et al. wrote, "[t]he debate about regulation of the cosmetics industry to protect the public health has gone unresolved for more than a century . . . The challenge for regulators is daunting; the global cosmetics industry is enormous, with an expected $265 billion in revenue in 2017. The Office of Cosmetics and Colors within the FDA's Center for Food Safety and Applied Nutrition [CFSAN] is tiny in contrast and, with a budget of around $13 million for Fiscal Year 2017, chronically underfunded, even considering its limited responsibilities and scope of authority . . . History has repeatedly shown that when there is insufficient regulatory oversight, a few unscrupulous people or companies will exploit the vulnerable public for profit . . . [a]lthough FDA oversight of drugs and medical devices has been substantially strengthened by later legislation, the lack of similar enhancements for cosmetics means that the cosmetic industry remains largely self-regulated . . .For cosmetics—and for dietary supplements—the FDA's oversight authority remains stuck at the levels established in 1938, nearly 80 years ago . . . The FDA is vastly underresourced for even the very limited

responsibility it currently has for the safety of cosmetics."[19]

40. In 2017, Kwa, et al. wrote, "[b]etter cosmetic surveillance is needed given their ubiquity and lack of a premarket approval pathway. Unlike devices, pharmaceuticals, and dietary supplements, cosmetic manufacturers have no legal obligation to forward adverse events to the FDA; CFSAN reflects only a small proportion of all events. The data suggest that consumers attribute a significant proportion of serious health outcomes to cosmetics. The lack of high-quality data leads to reactionary responses by the FDA subject to consumer pressure."[20]

41. In July 2018, Senators Dianne Feinstein and Susan Collins wrote in the Journal of the American Medical Association, "[t]here is no other class of products so widely used in the United States with so little regulation . . . [t]he lack of oversight is a broad threat to public health. . . As a result, US companies that market personal care products largely determine their own safety standards."[21]

42. On November 11, 2008, Anna Prilutsky, then Senior Director Research & Development at Johnson & Johnson, sent a PowerPoint from Lori Dolginoff, then Director, Global Communications at JNJ, containing "the latest version of the content for the Pure Truth website" which stated on a slide titled "Ingredients in JOHNSON's Baby products" that there is "[l]imited role of FDA." JNJ000367482-3.

43. In a December 2013 PowerPoint presentation, Defendant Imerys stated "[c]osmetics are different from foods and drugs and are governed by much looser regulation . . . Companies are in

[19] Califf, Robert M., Jonathan McCall, and Daniel B. Mark. "Cosmetics, Regulations, and the Public Health: Understanding the Safety of Medical and Other Products." JAMA Internal Medicine 177, no. 8 (August 1, 2017): 1080–82. https://doi.org/10.1001/jamainternmed.2017.2773.

[20] Kwa, Michael, Leah J. Welty, and Shuai Xu. "Adverse Events Reported to the US Food and Drug Administration for Cosmetics and Personal Care Products." JAMA Internal Medicine 177, no. 8 (August 1, 2017): 1202–4. https://doi.org/10.1001/jamainternmed.2017.2762.

[21] Feinstein, Dianne, and Susan Collins. "The Personal Care Products Safety Act." JAMA Internal Medicine 178, no. 5 (May 1, 2018): 601–2. https://doi.org/10.1001/jamainternmed.2018.0064.

charge of performing the analysis and conforming to the standards. The FDA requires no prior testing for cosmetic products." IMERYS 068497.

44. A 2009 JNJ memorandum regarding "Cosmetics Regulation" stated that "the oversight of the FDA is secondary to individual company responsibility to self-regulate in meeting these standards." JNJTALC00494340.

45. The memorandum continued, "[v]oluntary self-regulation of the cosmetics industry in the United States is not working. Consumers deserve a government that protects them from unsafe chemical exposures in the cosmetics they use every day." JNJTALC000494340 at 49.

46. In my opinion, a cosmetic manufacturer has a responsibility to substantiate the safety of their product or must warn consumers that the safety of their product has not been determined or not sell the product.

47. In my opinion, in addition, if a health hazard may be associated with the product, a cosmetic manufacturer must include a warning on their product.

B. The standards in the cosmetic industry to substantiate the safety of cosmetic products

48. Defendants have been long standing members of the Personal Care Products Council (formerly the CTFA). Deposition of Mark Pollack, August 29, 2018. 44:7-45:6; 62:15-64:2; 105:13-18; 110:12-21; 128:10-21; Prepared Statement of Pamela G. Bailey, President Personal Care Products Council, May 14, 2008, United States House of Representatives Committee on Energy and Commerce.

49. The CTFA established the Cosmetic Ingredient Review in 1976. "The Cosmetic Ingredient Review (CIR) was established in 1976 by the industry trade association with the participation of the U.S. Food and Drug Administration and the Consumer Federation of America. The CIR is the industry funded panel that reviews the safety of the ingredients used in

cosmetics today. Its meetings are open to the public and its findings and minutes are publicly available on its website." FLDI Primer on Cosmetic Regulation, P. 12, PCPC_MDL00000998 at 1012.

50. According to the CIR, the purpose of such review is " to determine those cosmetic ingredients for which there is a reasonable certainty in the judgment of competent scientists that the ingredient is safe under its conditions of use." [emphasis added] CIR Procedures Report June 2018, at 3.

51. The CIR has stated, "'Safe' or 'safety' means no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future, e.g., a low incidence of minor adverse reactions (as shown in animal or human testing or product experience). Such information includes, but is not limited to, the chemical structure of the ingredient, published and unpublished tests on the ingredient and products containing the ingredient, significant human experience on products containing the ingredient during marketing, and information on similar or related substances. A lack of information about an ingredient shall not be sufficient to justify a determination of safety." [emphasis added] CIR Procedures Report June 2018, at 2.

52. Executive Vice President and Legal and General Counsel Elizabeth H. Anderson and Associate General Counsel Farah K. Ahmed of the Personal Care Products Council authored the 2012 Food and Drug Law Institute's Primer on the Cosmetic Regulatory Process which states, "[c]osmetics are not subject to premarket approval by the Food and Drug Administration (FDA), but the product and ingredients must be tested for safety. If the manufacturer cannot substantiate safety, a warning is required . . . The 'intended use' doctrine states that cosmetic or drug status is

determined by claims about the intended use of the product." PCPC_MDL00000998 at 1004.

53. In my opinion, consistent with FDA regulations and statutes, a cosmetic manufacturer under the cosmetic industry standards must assure the safety of their ingredients. It is the responsibility of the cosmetic manufacturer to assure that there is reasonable certainty in the judgment of competent scientists that the product is safe. Safe as defined by the industry standards means "no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future . . .." Cosmetic Ingredient Review Procedures, October, 2010/June 2018 Part A – General, Section 1. Definitions. (m).

54. Thus, in my opinion, manufacturers have a responsibility to assure that there is reasonable certainty there is no evidence to suspect their cosmetic may pose harm. Furthermore, in my opinion, if there is evidence that there are reasonable grounds to suspect that the cosmetic product may pose harm for the proposed conditions of use, such product does not meet the industry standards for safety.

C. Defendants' statements that cosmetic manufacturers have responsibility to substantiate the safety of their product.

55. On January 26, 1994, Dr. Stephen D. Gettings, Director-Toxicology of the CTFA sent a final draft of a manuscript for presentation at a symposium [22] to the "Talc Interested Party Task Force," which included Dr. William Ashton and Michael Chudkowski (both at JNJ), as well as Dennis Christensen and Richard Zazenksi (both at Luzenac America, Inc., now Imerys). Dr. Gettings thanked the Talc Interested Party Task for members "for all your help" and stated he still had questions that he needs answered before he gives the presentation. In the attached

[22] The symposium, "Workshop on Talc: Consumer Uses and Health Perspectives" was held on January 31, 1994, at the National Institutes of Health. IMERYS_00057325.

manuscript, Dr. Gettings stated, "In the United States, the safety of cosmetic ingredients and finished formulations must be substantiated by manufacturers. Raw material suppliers also bear a responsibility for the safety substantiation of ingredients they supply to the cosmetic industry since Section 201(i) of the FD&C Act defines 'cosmetic' to include articles used as components of cosmetic products (21 U.S.C. 321(i))." IMERYS-A_0005946.

56. Dr. Gettings further stated, "The talc industry has a moral and legal responsibility to supply products that can be used safely . . . Talc facilities engaged in the manufacture of USP, FCC, or CRFA-grade talc products are subject to the general provisions of the FDC&C Act and are prohibited from introducing adulterated articles into interstate commerce . . ." IMERYS-A_0005946.

57. In a June 24, 2003, PowerPoint, JNJ stated that Johnson's Baby products are "assessed for safety based on the intended use." JNJTALC000777136.

58. On November 11, 2008, in the aforementioned email and PowerPoint presentation sent by Anna Prilutsky, Senior Director Research & Development at JNJ, Ms. Prilutsky stated, "The FDA requires an ingredient declaration on the product's packaging to enable you to make informed purchasing decisions . . . The FDA also requires that each ingredient used in personal care products and each finished product be adequately substantiated for safety prior to marketing. FDA regulations do not have prescriptive tests that manufacturers are required to follow to substantiate safety. The responsibility for determining and conducting appropriate tests to substantiate safety is that of the manufacturer. Furthermore, if the safety is not substantiated, the label must bear the statement: *Warning – The safety of this product has not been determined.*" JNJ000367482-3.

59. The same PowerPoint continued, "Our baby products are composed of a variety of ingredients obtained from reputable, trusted suppliers. We hold these suppliers to high standards

of material safety, purity and quality based on our best for baby standards. The safety and quality of these materials are critical to the success – how well they meet your needs – and safety of the final products. When we acquire raw materials and active ingredients from our suppliers, we don't simply take their word for the safety of ingredients. We rely on validated scientific proof of safety for individual ingredients and finished products. Every lot of every raw material is evaluated before it is released for use in any finished product. And we ensure that all ingredients comply fully with regulations in all countries where our baby products are sold." JNJ000367483.

60. In a June 1, 2010, PowerPoint presentation, sent by David Stanavage, then Senior Product Director, JNJ and Kathleen Wille, Manager, Regulatory Affairs, JNJ and meant to address concerns raised by retailer Walmart about what was "best for baby" and stated that it "assessed each ingredient that we consider for use in our personal care products for baby." JNJ 000438939-41. The PowerPoint continues, "[a]ll final baby product formulations are comprehensively assessed for safety . . . Johnson's Brand is responsible for the ethical management of health, safety, and environmental aspects of our products through their total lifecycle." JNJ 000438939-41.

61. The PowerPoint continued, "the FDA has limited resources and enforces according to the risk to public health. The FDA does not pre-approve personal care product labeling prior to marketing. It is the manufacturer's responsibility to ensure that labeling is accurate. We follow strict rules for nomenclature to ensure an accurate representation of the contents of our products." JNJ 000438941.

62. On October 15, 2012, Lorena Telofski testified on behalf of Johnson & Johnson that Johnson & Johnson goes "through a process to substantiate safety for the present use. If it doesn't meet the threshold of safety for present use, it is not going to go on the market."

201:198-23; *see* also 199:21-23.

63. On December 16, 2014, Jay Ansell, Vice President – Cosmetics Program, Personal Care Products Council (Formerly CTFA), sent an email stating his "primary concern" regarding the statement in a "Frequently Asked Questions" document for the Look Good Feel Better Program[23] that, "Cosmetic Ingredients are not required by federal or state laws to be tested for their contributions to the risks of acquiring cancer or other adverse health conditions from long-term use." Ansell continued that "While it is true that Federal law does not require 'Testing', Federal law absolutely requires the safety be substantiated. 21 CFR 740.10(a)." PCPC_MDL00122041.

D. Modernization of Cosmetic Regulation Act of 2022 (MoCRA)

64. At the end of the 117th Congress, the 102nd Session, Congress enacted the Consolidated Appropriations Act, 2023. As part of that omnibus appropriations, Congress enacted the Modernization of Cosmetic Regulation Act of 2022 (MoCRA). The implementation date for a number of these new requirements is December 29, 2023. FDA issued a new Guidance Document in November 2023, announcing that, "FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product facility registration and cosmetic product listing for an additional six months after the December 29, 2023, statutory deadline, or until July 1, 2024, to provide regulated industry additional time to comply with these requirements. In addition, FDA does not intend to enforce the registration requirement for owners or operators of facilities that first engaged in manufacturing or processing a cosmetic product after December 29, 2022, or the listing requirement for cosmetic products first marketed

[23] According to the Personal Care Products Council, the Look Good Feel Better program is offered as a collaboration of the Personal Care Products Council Foundation, the American Cancer Society, and the Professional Beauty Association that "teaches cancer patients how to cope with the appearance (related) side-effects of cancer treatment. PCPC_MDL00122043.

after December 29, 2022, until July 1, 2024." Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing, Guidance for Industry, U.S. Dept. of Health and Human Services, Food and Drug Administration, Office of Chief Scientist (OCS), November 2023.

65. While the new requirements are yet to be effective, it is important to note that the new legislation builds upon the concept of safety substantiation that currently exists in the regulation under 21 CFR 740.10. Prior to the implementation of MoCRA, 21 CFR 740.10 required companies to substantiate the safety of their product prior to marketing but, in lieu of safety substantiation, it permitted cosmetic manufacturers to label the Warning disclaimer. The new legislation requires companies to adequately substantiate that a cosmetic product is safe and maintain records to support such representations. There is no Warning that can substitute for substantiating the safety of the product.

66. Both in the past and going forward, cosmetic manufacturers must substantiate the safety of their product.

III. DEFENDANTS DID NOT SUBSTANTIATE THE SAFETY OF THEIR TALCUM POWDER PRODUCTS IN LIGHT OF QUESTIONS ABOUT ASBESTOS, NON-ASBESTIFORM AMPHIBOLES, AND FIBROUS TALC IN THEIR PRODUCT

67. In my opinion, once JNJ had evidence of a) the presence of asbestos because of its known carcinogenicity and absence of a threshold dose; or b) the presence of non-asbestiform amphiboles or fibrous talc, the safety of their product was not established.

68. In my opinion, beginning in the 1970's, the safety of JNJ's talcum powder products had not been substantiated, consumers were not warned of potential health risks, and there was a reasonable basis to believe that such an association between the product and health risks existed.

69. In my opinion, beginning in the 1970's, because the safety of their product was not

established, their talcum powder products should not have been sold.

A. Asbestos is a known carcinogen

70. According to the National Cancer Institute, "Asbestos has been classified as a known human carcinogen (a substance that causes cancer) by the U.S. Department of Health and Human Services (HHS), the U.S. Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC)."[24]

71. According to the International Agency for Research on Cancer (IARC), "There is *sufficient evidence* in humans for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite). All forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) are *carcinogenic in humans*." (IARC, "Asbestos (Chrysotile, Amosite, Crocidolite, Tremolite, Actinolite, and Anthophyllite," p. 294).

72. In regard to asbestos, talc containing asbestos, and talc containing asbestiform fibers (fibrous talc), IARC published Monograph 100c, which found that, "[t]here is sufficient evidence in humans for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite). Asbestos causes mesothelioma and cancer of the lung, larynx, and ovary . . . There is sufficient evidence in experimental animals for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite). All forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite) are carcinogenic to humans (Group 1)." "The conclusions reached in this Monograph about asbestos

[24] *See*, Agency for Toxic Substances and Disease Registry. *Toxicological Profile for Asbestos*. September 2001. Retrieved April 18, 2017, National Toxicology Program. Asbestos. In: *Report on Carcinogens. Fourteenth Edition.* U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, 2016. U.S. Environmental Protection Agency. *Health Effects Assessment for Asbestos.* September 1984. EPA/540/1-86/049 (NTIS PB86134608). Retrieved April 18, 2017. IARC Working Group on the Evaluation of Carcinogenic Risk to Humans. Arsenic, Metals, Fibres and Dusts Lyon (FR): International Agency for Research on Cancer; 2012. (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, No. 100C).

and its carcinogenic risks apply to these six types of fibres wherever they are found, and that includes talc containing asbestiform fibres." IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 100c, 2012.[25]

73. In 2010, IARC published Monograph 93, which found that "[t]he relative risks for ovarian cancer among users of body powder (versus non-users) were homogenous across this relatively diverse set of eight studies, each of which indicated a 30–60% increase in risk . . . Perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B)." "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 93," 2010. This monograph specifically addresses the safety of talc not containing asbestiform fibers.

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[25] In IARC 100c published in 2012, "the Working Group noted that a causal relationship between exposure to asbestos and cancer of the ovary was clearly established, based on five strongly positive cohort studies of women with heavy occupational exposure to asbestos [references omitted]. The conclusion received additional support from studies showing that women and girls with environmental, but not occupational exposure to asbestos [references omitted] had positive, though non-significant, increases in both ovarian cancer incidence and mortality"

Since IARC's review, while published in 2012, included studies through 2009, there have been three meta-analyses regarding asbestos exposure and ovarian cancer risk:

In 2011, Camargo, et al. performed a meta-analysis of 18 cohort studies of women occupationally exposed to asbestos. "The overall pooled SMR [standardized mortality ratio] estimate for ovarian cancer was 1.77 (95% confidence interval, 1.37-2.28) . . . Our study supports the IARC conclusion that exposure to asbestos is associated with increased risk of ovarian cancer." Camargo et al. Occupational exposure to asbestos and ovarian cancer: a meta-analysis. *Environ Health Perspect.* 2011;119:1211-1217.

In 2011, Reid, et al. also performed a meta-analysis to "quantify the evidence that exposure to asbestos causes ovarian cancer." . . . "Fourteen cohort and two case-controlled studies were identified. . . When all studies were included in a meta-analysis, the effect size was 1.75 (95% CI, 1.45-2.10 attenuating to 1.29 (95% CI, 0.97-1.73) in studies with confirmed ovarian cancers. The authors "suggest that the IARC decision was premature and not wholly supported by the evidence." Reid et al. *Cancer Epidemiol Biomarkers Prev*.; 21(7) July 2011.

More recently in 2021, the German Medical Expert Advisory Board on Occupational Diseases at the Federal Ministry of Labour and Social Affairs (BMAS) conducted its own meta-analysis. This meta-analysis yielded an overall SMR of 1.88 (95% CI 1.47-2.39). "If the distinction is made according to "ovarian cancers confirmed", as in Reid et al., a pooled effect estimate of 1.89 (95% CI 1.40-2.55) is obtained for the studies without histological verification of ovarian cancer and a pooled effect estimate of 1.98 (95% CI 1.32-2.97) for those with histological confirmation of ovarian cancer. The difference is thus negligible (p>0.8.)." Nowak, et al. *Asbestos Exposure and Ovarian Cancer – a Gynaecological Occupational Disease*. Background, Mandatory Notification, Practical Approach. Published online 2021 May 20. doi: 10. 1055/a-1361-1715.

i. No safe threshold for asbestos

74. According to a Rio Tinto Minerals presentation, "Talc: Asbestos Issues and Management," "Asbestos has long been considered a human carcinogen" J&J 252.

74.1. "Because there is no recognized 'safe' level of exposure to asbestos, the presence of any amount in talc would be a serious problem." J&J 252.[26]

75. According to OSHA, "There is no 'safe' level of asbestos exposure for any type of asbestos fiber."[27]

76. NIOSH, similarly, states, "Evaluation of all available human data provides no evidence for a threshold or for a 'safe' level of asbestos exposure." ("WORKPLACE EXPOSURE TO ASBESTOS Review and Recommendations," DHHS (NIOSH) Publication No. 81-103, November 1980).

[26] *See* also, Trial Testimony of Susan Nicholson in *Prudencio v. Johnson & Johnson*, RG20061303, June 18, 2021, at p. 964 ("Q. Are you aware of there being a safe level of exposure to asbestos? MS. BROWN: Objection. Beyond the scope. Calls for expert opinion. THE WITNESS: Well, as an expert, I could opine on that. Our policy at Johnson & Johnson is no asbestos in our products. So our company position is no asbestos is safe"); Trial Testimony of Dr. John Hopkins in *Weirick v. Brenntag North America, Inc.*, JCCP 4647, Case No. BC656423, April 11, 2018, at p. 108-109 ("Q Okay. And Johnson & Johnson knows there's no safe level of asbestos exposure, especially for children, correct, sir? MR. BICKS: Objection to the form. No foundation. A. Again, there is no known safe level. Q. That's right. Especially for children, correct? A. Yes."); Trial Testimony of Dr. John Hopkins in *Barden v. Brenntag North America, et. al*, MID-L-0932-17AS, July 22, 2019, at p. 48-49 (Q "Johnson & Johnson knows there is no safe level of asbestos exposure, correct? A. Scientists have not shown a safe level. So, yeah, I would not disagree. Q. There is no known safe level of asbestos exposure, especially, for children, correct? A. Again, same answer. There's no -- no evidence to say otherwise, so we'll assume it's correct. Q. Well, in fact, your answer, if you could go right below on Page 108, you were asked this question. "Okay, and Johnson & Johnson knows there's no safe level of asbestos exposure, especially for children, correct, sir?" And your answer was again, "There is no known safe level," correct? A. Yes. That's what I said. Q. And then the followup question was, "That's right, especially, for children, correct?" And you said, "yes," correct? A. That's right. That's what I agree, yeah.").

[27] *See* Skammeritz, E. et al. "Asbestos Exposure and Survival in Malignant Mesothelioma: A Description of 122 Consecutive Cases at an Occupational Clinic." *The International Journal of Occupational and Environmental Medicine (IJOEM)*, Vol 2, No 4 October 2011., Greenberg M., Davies L, T. A. Mesothelioma Register 1967-68. *British Journal of Industrial Medicine,* 31, 91-104, 1974, Asbestos (Actinolite, amosite, anthophyllite, chrysotile, crocidolite, tremolite). World Health Organization (WHO), International Agency for Research on Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans, Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42, Supplement 7, 1998.

77. Per the World Health Organization, "No safe level can be proposed for asbestos because a threshold is not known to exist."[28,29]

B. Definition of asbestos

78. Asbestos is the generic commercial designation for a group of naturally occurring mineral silicate fibers of the serpentine and amphibole series. These include the serpentine mineral chrysotile, and the 5 amphibole minerals – actinolite, amosite, anthophyllite, crocidolite and tremolite. IARC Monogr Eval Carcinog Risk Chem Man. 1973;2:1–181.

79. Johnson and Johnson, from the 1960's through 2019, defined asbestos as follows:

79.1. "Asbestos is defined to be the fibrous serpentine, chrysotile and the fibrous forms of the amphibole group as represented by amosite, anthophyllite, crocidolite, tremolite asbestos and actinolite".[30]

C. The safety of nonasbestiform amphibole was and still has not been established

i. Geological relationships between asbestos and talc

80. According to Rio Tinto Minerals, as documented in a presentation in June 2009 titled "Analytical Capabilities and Test Methods," there are different pathways that lead to the formation of talc. They cite the following breakdown of Talc Deposit mineralization by world production (IMERYS 300644, at p. 10):

[28] WHO Air Quality Guidelines 2nd edition http://www.euro.who.int/document/aiq/6_2_asbestos.pdf
[29] https://www.niehs.nih.gov/health/materials/asbestos_508.pdf
[30] *See* 4/21/64, Johnson & Johnson Baby Products Company Material Specification for Windsor 66 Talc, Bates labeled JNJNL61_000021162 (DX7144), 1/28/77, J&J Audit Testing of Windsor 66 Talc for Asbestos, Bates Labeled J&J-0086339, 2/23/78 Letter from J&J's George Lee to R. N. Miller, Bates labeled JNJ 000285031 (J&J 159), JJCPI Authorization for Interim Specification 11/20/1989, amended 6/5/91, Bates labeled JNJMX68_0000000440, 9/23/97 Material Specification for Windsor Grade 66 Talc by Luzenac America, Inc., Bates labeled JNJAZ55_000020366, Imerys certificate of analysis dated 11/30/2017, Bates labeled JNJTALC0000580245, Imerys certificate of analysis dated 2019, Bates labeled JNJTALC001427814.

a. 20%= Serpentine Host Rock (RTM Vermont, Ontario) Potential for serpentine asbestos

b. <10% = Amphibole-bearing host rock* (non-RTM; New York State) Potential for amphibole asbestos

c. 10% = Meta-sedimentary host rock (RTM Trimouns, France)

d. 60% = Mg-rich carbonate host rock (RTM Montana, Chinese Guangxi)

81. According to another Rio Tinto Materials presentation, "All talc deposits have the risk of localized asbestos occurrence if isolated metamorphic events (intrusion, etc.) occur in or near the deposit." (IMERYS_422064).

82. A September 13, 2011 presentation, titled "Fiber Management Overview," asked the question, "Can asbestos occur with talc?" The slide answered that question by stating (PLT-04451-0001, at p. 8):

82.1. "Talc derived from a metamorphic host rock can contain amphiboles and serpentine

82.2. "Ultramafic (serpentine) host rocks can contain chrysotile.

82.3. "All types: localized metamorphic events can produce amphiboles."

83. At a U.S. Food and Drug Administration Public Meeting: Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc on February 4, 2020, Dr. Bradley Van Gosen from the United States Geological Survey described "the mineral fibers that can be naturally intergrown with talc and show that their presence or absence is based on the mineral deposit type, that is the geologic conditions that form the talc deposit." (U.S. Food and Drug Administration Public Meeting: Testing Methods for Asbestos in Talc And Cosmetic Products Containing Talc,. In a slide deck and published article, Dr. Van Gosen stated,

83.1. "Talc formation. Talc is a replacement mineral – It replaces a preexisting magnesium-rich mineral." (p.10).

83.2. "This process can be driven by:

* Regional metamorphism (tectonics)

* Contact metamorphism (igneous intrusion)

* Circulation of magmatic hydrothermal fluids (heated by magma at depth)." (p.10).

83.3. "The geologic environments that form asbestos bring together magnesium and silica in solution, the same chemistry that forms talc." (p. 9).

83.4. In the article titled "Using the geologic setting of talc deposits as an indicator of amphibole asbestos content," Dr. Van Gosen states, "Talc deposits are products of metasomatism caused by regional metamorphism, contact metamorphism, or hydrothermal metamorphism (meteoric fluids or brines heated by distant or buried intrusion).

83.5. "A number of U.S. talc deposits of commercial size (under past or present economic conditions) were formed by metasomatic processes driven by regional metamorphism; these large bodies consistently contain talc intergrown with amphiboles, such as tremolite and (or) anthophyllite. Debate over the asbestos mineral content (major versus trace amounts) within these talc-amphibole deposits is the result of differing interpretations of the predominant habit (asbestiform versus non-asbestiform) of the amphibole particles." (p. 920).

83.6. "The host rock composition and process of formation determines the qualities of talc, which in turn affects the industrial applications of a particular deposit. The grain size and shape, color, and purity of talc influence its uses (Piniazkiewicz et al. 1994).

83.7. "In addition, the talc-forming mechanism – hydrothermal processes, contact metamorphism, or regional metamorphism – directly influenced the ultimate amphibole content of the talc ore body, described below through examples. Within a single mineral deposit, such as some talc ore bodies, amphibole crystals may range in habit from blocky to prismatic to acicular to asbestiform." (p. 922).

83.8. "Talc deposits in Vermont are typical "black wall" deposits, formed by regional metamorphism and metasomatism of ultramafic rocks, originally composed of dunite or peridotite.

83.9. "These deposits form as zoned alteration "rinds" around ultramafic bodies; the altered zones can be 6.5 km or more long and 460 km wide (Cady and others 1963)" (p. 933).

83.10. "Black-wall talc deposits are associated spatially with serpentine masses that in some areas host well-developed chrysotile asbestos (Bain 1942; Cady and others 1963). The alteration zone locally contains actinolite, tremolite, anthophyllite, and (or) cummingtonite, as described by Cady and others (1963)." (p. 934).

83.11. At the FDA meeting, Dr. Van Gosen stated, "Talc and anthophyllite form in the same – can form in the same geologic environment. You'll see that magnesium, silica, and water are the essential ingredients to form both talc and the asbestos minerals." (p. 27:5-9).

83.12. Dr. Van Gosen further stated, "When an amphibole bearing rock, including talc is pulverized, micronized, and put into a product, it can be difficult to determine whether a very small, thin, elongate amphibole particle that you observe, even under high magnification, whether it represents a cleavage fragment or instead is a fiber that was once part of a fiber bundle. And just to complicate matters, some amphibole particles, such as this example in the lower right, can display characteristics of both fibers and cleavage fragments." (p. 29:10-21).

83.13. "The same geologic processes that form talc can also form amphiboles, sometimes including the asbestiform varieties of the amphiboles." (p. 30:1-4).

83.14. In 2020, Van Gosen at the FDA Public Meeting suggested "…that a very detailed mineralogy examination of the talc ores from this deposit types, taken from samples at the mine site, is a study that should be undertaken." (p. 39:14-17). He further stated, "that it would be much easier to determine the amphibole and chrysotile content of a talc that was used in a commercial product, including cosmetics, if the mineralogy was examined from samples that were collected in place at the mine site before the talc rock had been mined, pulverized, micronized, and then mixed into a product where the mineral particles now, including fibers are now extremely small and scattered, and are difficult to observe or to analyze." (p. 44:1-11).

83.15. In comments submitted to the FDA as part of the public docket, Dr. Laura Webb, a professor of geology at the University of Vermont, and a Defendant expert witness in this matter, stated with regard to Dr. Van Gosen's publication in 2004 and 2005, "Although a good summary, one cannot accept at face value generalizations about the association of talc and amphibole asbestos made by Van Gosen [citation omitted]. That is, those generalizations are not representative of an exclusive suite of talc ores formed under conditions favorable neither to chrysotile or amphibole asbestos formation (or preservation). One must in fact understand the details of the local and regional geology of any give [sic] mine – including the potential for a complex distribution of rocks of different metamorphic grades resulting from complex tectonic history." (Webb, "Comments on Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc, FDA-2020-N-0025," p. 12).

84. In an email dated January 30, 2008, from Rio Tinto Materials Regulatory Affairs Manager Richard Zazenski to colleagues Peter Argust, Julie Pier, and Greg Hunter, Mr. Zazenski stated:

84.1. "Geologically, it doesn't make sense to me that you can have a mineral deposit that just contains 'non-asbestiform' tremolite. I believe the USGS study of talc from Death Valley, California, nailed it correctly that if a deposit contains 'non-asbestiform' tremolite, there is also asbestiform tremolite naturally present as well. And since tremolite was never really a large commercial mineral such as chrysotile or crocidolite, there is not enough medical data to conclude that 'blocky' tremolite is simply a nuisance dust. But that has been the story line for Vanderbilt for years and they're sticking to it.

84.2. "I closely followed the OSHA/Vanderbilt debate during the 1980's and early 1990's. Essentially, OSHA 'threw in the towel' rather than expend their limited resources any longer on this issue. Their decision by no means should be interpreted as a vindication of Vanderbilt's arguments." IMERYS 442002-4.

85. A confidential report of the Geology Section, Windsor Minerals, Inc. by William J. Gregg dated February 20, 1978, written "under the direction of R. Roger N. Miller, President of Windsor Minerals" stated, "the amphibolites in the Moretown usually occur not more than 100 to 200 meters away from the ultramafics and are generally more abundant than the amphibolites in the Cram Hill. In rarer cases very thin amphibolite layers less than 1 foot thick may run parallel to the ultramafic zone at less than 2 feet from the contact. These rocks are medium to coarse-grained and may occur as strongly layered lenses or larger, unlayered bodies up to 1 meter thick. The rocks contain abundant blue-green amphibole and albite, and minor amounts of carbonate, chlorite and opaque minerals". IMERYS 437016.

85.1. "The amphibolites within the Cram Hill usually occur within 10 to 20 meters of the ultramafic zone. They are usually fine-grained rocks composed of blue-green pleochroic amphiboles, albite, carbonates and chlorite in varying proportions. The feldspathic and carbonate

minerals are often segregated in layers with little or no amphiboles present. These layers are the dominant element of the earliest compositional layering recognized in the amphibolite (S_0). This layering is disposed in tight to isoclinal early folds and is later refolded by open folds. (Fig. 9) IMERYS 437013.

85.2. A photographic image demonstrating the layering in the amphibolites of the Cram Hill is shown in Figure 9. IMERYS 437017.

86. A Literature Review of Geology and Mineralogy of the Vermont Talcs started with general description of the authigenesis of talc mineral and stated "The authigenesis of 'pure talc' mineral, Mg_3 $[Si_4 0_{10}]$ $(OH)_2$ is generally represented as being the end member (lowest free energy) of a long chain of mineralogical or geothermal or geochemical alterations (weathering events) taking place along very diverse paths depending basically on the geothermal and geohydraulic conditions of exposure over many millions of years. However, there is general agreement that the basic chain of events was about as follows:

86.1. "An intrusive ultramafic (high in magnesium) magma which is essentially magnesian silicate glass with a large number of minor associated constituents;

86.2. "Crystallization to a 'serpentine' or 'serpentinite' which is not a mineral but is a rock name for a rock formation with a high magnesium silicate content. The serpentines may alter or crystallize by a number of hydrothermal, geothermal, or a combination of sequences or reactions requiring ionic mobilities, disporportionations, solution replacements, etc., into a rather wide variety of recognizable and identifiable crystallographic types or 'minerals.' The most common of these are the platy hydrous magnesium (2-layer) phyllosilicates, antigorite or lizardite; the rare form of this group is the fibrous (asbestiform morphology) chrysotile. Other related minerals commonly found associated with the crystalline serpentine minerals are those few amphibole

structures - - tremolite, actinolite, and rarely, anthophyllite which are some of the crystallographically recognizable forms of the amphibole rock formations.

86.3. "Under certain conditions all of these minerals, depending on temperature, pressure, ground water solutions, and/or other factors, alter first to chlorite, then to carbonates or dolomite, and finally to talc; there is some debate whether dolomite precedes talc or both are formed more or less simultaneously from the chlorite and there can be said to be evidence for both sequences. In some cases the dolomitic limestone is well separated from the steatite (talc); in other cases, there is much intermixing in various proportions where the ore is generally known by the miners as 'grit'. The important aspect of these series of alterations is that talc is always the lowest free energy end-member and the alteration sequence has never been observed to go in the opposite direction. In many cases, however, there may be isomorphous replacements by talc of the preceding mineral morphologies, as well as occasional unaltered relicts of preceding mineral species.

86.4. "The so-called "black-wall chlorite" is in fact the geochemical transition zone between the serpentine or other host rock and the talcose series replacements. This transition zone (the blackwall) may vary from a few inches to several free in thickness and 'fingers' or extensions of it may occasionally intrude into the talc ore body. It is at this transition interface that the associated minerals, i.e., chlorite, tremolite, actinolite, and rarely, chrysotile, may be found. Occasionally some small parts of this materials is mined and mixed up along with the talc ore. The blackwall is thermodynamically and geothermally only metastable and it moves very slowly as the replacements and transitions occur as described above through geologic time." JNJ000263852.

87. A chart titled "Vermont Rock Type Code" identify as accessory minerals "amphiboles" on the first and second page. IMERYS 426609.

88. A memo from J.J. Godla and D. G. Ogden to J.S. Forbes dated January 5, 1988, re: Visit to Ludlow, VT operations of Windsor Minerals, Inc. with Roger Miller, President and Winston Dezaine, Mine Supt. December 31, 1987, stated under a section titled Argonaut Mine: "The bladed amphibole mineral actinolite was observed in numerous areas within the chlorite schist inclusions." In the General Comment section the memo states:

88.1. "As far as asbestos problems [sic] are concerned, Miller states that he has been sampling all mine ore and produce shipped for 14 years. Composites have been submitted to McCrone Laboratory in Chicago, and no asbestiform minerals have been reported. The amphibole, actinolite (bladed) was observed in the chlorite schist inclusions and wall rock at all of the Ludlow mining operations." IMERYS 542268.

89. A document entitled Windsor Minerals, Inc. "Geology of the Talc Mine at East Johnson, Vermont" incorporated a thesis written by Barry O. Seymour titled "Geology of the Talc Mine at East Johnson, Vermont." JNJ 000287099. The thesis stated:

89.1. "As mentioned earlier, serpentinization is much less intense in Quebec, than in the north-central Vermont area, and most deposits contain a combination of talc and asbestos, instead of just talc." JNJ 000287264.

90. A Luzenac February 2010 report written by E.F. McCarthy titled Talc Geology, Mining and Processing for Cosmetic, Pharma and Food Applications, included a table titled Talc Ore Mineralogy (Cosmetic Source), which included columns for Montana, Vermont, Australia, China, and India. Under the heading "China", a row titled "Tremolite" reported "0-5" and a row titled "Serp'tine" reported "trace". IMERYS 081025.

ii. Distinguishing asbestos, non-asbestiform amphiboles and talc

91. According to the Rio Tinto Materials presentation, "Analytical Capabilities and Test Methods," the slide "Asbestos is a possible trace contaminant in talc" states it is "difficult to

determine if individual fibers were originally associated with a bundle (may be disaggregated from milling and/or sample prep)." IMERYS 448613 (p. 14).

91.1. The presentation went on to state:

a. "Talc vs. Chrysotile [Identification]: Easy! (p. 15).

b. Serpentine Interpretation: Easy! (p. 16).

c. Amphibole Interpretation: May be difficult…" (p. 17).

91.2. According to this industry presentation, there is an overlap of the Amphibole Fiber Mean Aspect Ratio between tremolite cleavage fragments and tremolite asbestos fibers. (p. 18).

91.3. According to this presentation, elongated mineral particles are fibers which are "a regulated term defined by aspect ratio and length – varies according to method/regulation," which include a subset that are asbestiform and a further subset that are asbestos. (p. 12).

92. Another presentation by Rio Tinto Materials, "Talc: Asbestos Issues and Management," stated:

92.1. "It is not known whether cleavage fragments of similar dimensions to asbestiform fibers pose the similar health risks.[31]

92.2. "On a microscopic scale, one cannot distinguish between asbestiform and cleavage fragment.

92.3. "Deposits can contain both asbestiform and non-asbestiform particles." J&J 252 (p. 11).

93. According to a presentation by the RJ Lee Group, Inc. on January 29, 2009 titled "What is Asbestos? Analytical Methods for Asbestos," RJ Lee stated, "Controversy over whether asbestos

[31] As I have stated previously, I am not offering any causation opinions regarding the health effects of cleavage fragments.

and non-asbestos elongated mineral particles have different biological and health effects." IMERYS 441186.

94. According to an official statement from The American Thoracic Society titled "Health Effects of Tremolite" dated June 1990 and distributed by the American Mining Congress, "A troublesome issue has been the mineralogical distinction between fibers and cleavage fragments, and whether this distinction has biological implications." IMERYS-MDL-AB_000194. The American Thoracic Society statement went on to state,

94.1. "…the focus on tremolite has raised the issue of the importance of cleavage fragments as opposed to asbestiform fibers. The issue, fundamentally, is whether two fibrous particles of identical size and shape will have different biologic properties if the particles are pieces of mineral which have broken off a larger sample parallel to a crystal face (i.e., cleavage fragments) as opposed to particles which have originally grown in a fibrous habitat (i.e., asbestiform fibers).

94.2. "It became apparent both from our review of the literature and from submissions made to this Committee by experienced mineralogists, that the distinction between cleavage fragment and asbestiform fibers, although theoretically clear, is in practice extremely murky. Some mineralogists believe that these two types of particles are always distinct, whereas others believe they shade off one into the other, and that intermediate forms (byssolite) exist. Further, these same submissions were at odds with each other in identifying particular samples used in various experiments (including the play sand samples analyzed by members of the Committee) as asbestiform fibers or cleave fragments. To complicate matters, it was also suggested to us that the important distinction is not that between cleavage fragments and asbestiform fibers, but between non-asbestiform and asbestiform fibers.

94.3. "Because of the lack of consensus among mineralogists, as well as the limited information about the minerals present in most published human and animal data (i.e., whether the particles used or observed really are fibers or cleavage fragments), we have to a great extent ignored the distinction, and ended up treating most of the data as based on 'fibers' of various sizes. The Committee recognizes that this is not an ideal solution, and where stronger evidence for the cleavage fragment or asbestiform nature of a particular fiber exists, we have noted it. However, until there is reasonable mineralogic unanimity both on general definition and the classification of specific samples, and then animal experimentation with such classified materials, it appears to us impossible to draw general conclusions about biologic effects based on the distinction between cleave fragments and asbestiform fibers." IMERYS-MDL-AB_0001941.

94.4. The society concluded, "Unquestioned health effects of tremolite asbestos have been demonstrated in both man and animals. These effects are identical to those produced by other forms of asbestos.

94.5. "There may be important physico-chemical distinctions between asbestiform and non-asbestiform tremolite dust particles. However, there appears to be considerable controversy in applying these mineralogic definitions to specific samples of mineral, particularly individual particles viewed microscopically after collection by air sampling or found in human lung, or when used experimentally.

94.6. "The evidence for biological effect distinctions based on mineralogical parameters, other than fiber dimension and fiber number, is currently inadequate.

94.7. "At present, the prudent public health policy course is to regard appropriately sized tremolite 'fibers,' in sufficient exposure dose (concentration and duration), as capable of producing

the recognized asbestos-related diseases, and they should be regulated accordingly." IMERYS-MDL-AB_0001953.

95. In the correspondence section in the British Journal of Industrial Medicine dated 1991, author Dr. B.W.K from the University of Pittsburgh said three questions needed to be answered before non-asbestiform tremolite could be "let off the hook" from a health perspective: "Firstly, can 'non-asbestiform' fibres, by mineralogical definition, be unambiguously identified to the satisfaction of experts and regulators? Secondly, if they can be identified, are they present to the exclusion of 'asbestiform' fibres in the same mix? Thirdly, if both of the previous conditions can be satisfied, do they inform as to the biological effects of long, thin, durable fibres that do not meet the crystallographic growth characteristics for asbestiform nature required by some experts? The answer to all three questions-without tergiversation-is no." JNJ00000049.

95.1. They concluded, "Until there is actual evidence, that 'non-asbestiform' fibres are easily defined, clearly separated from tremolite asbestos in real world work environments, and not productive of lung fibrosis or other health effects, it seems folly to declare them exempt from regulation." JNJ00000049-50.

95.2. According to an Executive Summary of Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc, dated January 6, 2020, written by US federal government subject matter experts on the (IWGACP[32]):

95.3. "The difficulty of identifying and quantifying individual asbestos or other mineral particles present at low concentrations in talc is compounded by the presence of non-asbestiform

[32] The IWGACP, Interagency Working Group on Asbestos in Consumer Products, is made up of subject matter experts from eight federal agencies: Dept. of Health and Human Services (including experts from Food and Drug Administration (FDA), National Institute of Occupational Safety and Health (NIOSH), and National Institutes of Health (NIH)/National Institute of Environmental Health Sciences (NIEHS)), Dept. of Labor: Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), Dept. of the Interior: U.S. Geological Survey (ISGS), and Dept. of Commerce: National Institute of Standards and Technology (NIST). *IWGACP Public Meeting, 4 February 2020*.

analogs with the same elemental composition and crystal structure, but different growth habit. Using TEM, differentiation of chrysotile from non-asbestiform serpentine analogs is relatively straightforward; however, each of the non-asbestiform amphiboles can disaggregate into particles resembling asbestiform fibers, giving rise to disputes between laboratories over whether elongate amphibole particles are truly asbestos, or are particles resulting from attrition of larger particles of a non-asbestiform analog. Because both types of elongate minerals are suspected of having biological activity with similar pathological outcomes, the distinction is irrelevant. Lack of consensus concerning what should be called 'asbestos' has persisted since the first reports indicating that asbestos might be present in talc used in cosmetics and has inhibited thorough toxicological and epidemiological investigations of disease attributable to talc that contains asbestos." (p. 3)[33].

96. According to the White Paper, "IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc" that provided "the scientific opinions of subject matter experts (SMEs) from an interagency working group related to testing cosmetic products containing talc and talc intended for use in cosmetics for the presence of asbestos, as well as other potentially harmful amphibole particles that can affect cosmetic product safety" (p. 4). That White Paper stated,

96.1. "The difficulty of identifying and quantifying amphibole asbestos particles in talc is compounded by the potential presence of amphibole particles that have the same elemental composition and crystal structure as one of the asbestos minerals but may have originated from their non-asbestiform analogues. (See Appendix D) The characteristic feature of an 'asbestos structure' is the 'bundle' consisting of multiple particles that may show definitive characteristics

[33] See JNJTALC0015234748

of asbestos particles such as splaying or longitudinal splitting at either end of the structure. However, asbestos structures are less readily identifiable after extensive processing that can result in attrition, such as milling of talc to produce cosmetics. In the milling process, non-asbestos amphibole particles in the ore can be reduced in size, resulting in particles that may look like asbestos." (White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc, p. 14).

96.2. According to Appendix D of the White Paper (p. 29), forces "applied to prismatic amphibole crystals can result in perfect cleavage along planes of weakness, often referred to as cleavage fragments. Similarly, attrition of bundles of asbestiform amphibole fibers can lead to structures such as the fibrils." Appendices to White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc (p. 33).

96.3. Appendix D went on to state, "Alternatively, fracture at points of structural weakness caused by defects in amphibole crystals can result in particles having random shapes. Consequently, significant variation in morphology of amphibole particles can occur even within a mineral deposit and it may be difficult to classify individual particles as being asbestiform or non-asbestiform." (p. 34)

96.4. It further stated, "Because fiber bundles undergo attrition, it is difficult to draw conclusions about the (asbestiform/non-asbestiform) habit of any individual amphibole particle at the levels of magnification afforded by electron microscope." (p. 36).

97. Appendix E of the White Paper titled "Health-Based Characteristics to Address Impacts of Asbestos and Other Elongate Mineral Particles in Talc Intended for Use in Cosmetics," stated the following:

97.1. "Asbestos is a known human carcinogen…there is no established threshold for health effects from asbestos exposure.

97.2. "These effects are rarely seen acutely but are more likely to occur many months or years following exposure.

97.3. "The specific biological mechanisms underlying asbestos and other elongate mineral particle (EMP) [footnote omitted] induced inflammation and/or diseases in humans and other animals remain uncertain… a more complete understanding of particle characteristics associated with activation of these biological mechanisms is lacking…

97.4. "Decisions to limit elongate particle size definition to specific size fractions (e.g., length >5 μm; width > 0.2 μm, and aspect ratio >3:1) were established for the convenience of using light microscopy to estimate exposures in occupational environments [citation omitted]. Thus, while it may be a useful index for exposure in certain situations, 'the fiber counting protocol using a 3:1 aspect ratio and a length of 5 μm or greater as being in some way a definition of asbestos has no scientific basis.'

97.5. "Particle size, tensile strength, morphology, chemical composition, bio-persistence, surface charge, surface porosity, and reactivity have all been implicated in the pathogenic processes associated with EMP exposure. (HEI 1991). Our general understanding of the mechanisms and progression of EMP-related disease comes from studies about biophysical, cellular, animal, and human responses to exposure. (NATO 1990, Fubini and Arean 1999, Xu, Zhou et al. 2002). Elongate particle interactions with cellular components can result in aberrations in cell division (Livingston, Rom et al. 1980, Achard, Perderiset et al. 1987, Renier, Levy et al. 1990, Korkina, Durnev et al. 1992), generation of reactive oxygen species (Brown, Fisher et al. 1998) and an inflammatory response (Shukla, Ramos-Nino et al. 2003, Mossman 2018, Pfau,

McNew et al. 2019). Several studies in animal models report that longer fibers are more strongly associated with cancer incidence (Stanton M.F. and Layard 1981, Davis, Addison et al. 1991, Berman,Crump et al. 1995).

97.6. "Particle size, aspect ratio (length-to-width ratio), dissolution characteristics, and cellular processes affect exposure. Additionally, anatomy and physiology of the host, internal distribution, retention, and clearance from the body are all determinants of internal exposure. (CDC/NIOSH 2011).

97.7. "Generally, thinner particles with higher aspect ratios, may penetrate more deeply into the lungs (Timbrell1982, Lippmann 1990, Bernstein, Rogers et al. 2011). Larger particles and those with higher density may impact the nasopharyngeal region of the upper airways, where they are more efficiently removed from the respiratory tract…

97.8. "…censored exposure indices are not capable of, nor were intended to, be used in context of consumer exposure to the presence of asbestos in cosmetics.

97.9. "More than four decades ago (prior to the practice of indexing fibers), the CDC/NIOSH fully characterized the presence of EMPs (including subsets of regulated asbestos and asbestiform minerals), in a talc mining and milling operation in St. Lawrence County, New York; where morbidity and mortality was significant in workers exposed to dusts (NIOSH1980). It was observed that 97% of the worker exposures to tremolite and 90-92% of the worker exposures to anthophyllite were to fibers <5 μm in length, well below the size range commonly recorded by less sensitive light microscopic techniques.

97.10. "Once inside the body through inhalation, ingestion, or perineal exposure, EMPs can migrate through tissues and organs to secondary sites of exposure where progressive cell damage can occur (Cook and Olson 1979, Wehner 1994, Heller, Westhoff et al. 1996). The risks

of irreversible damage to cells and tissues of the body following exposure are associated with the accumulation of elongate particles in susceptible tissues. Retention and accumulation of elongate particles in biological tissue is influenced by the nature of the EMP, magnitude of the exposure, host physiology, type of tissue, migration and transformation of particles within the body, and clearance of particles through cellular mechanisms, including dissolution and removal by alveolar macrophages.

97.11. "Research findings of Stayner et al. (2008) show that cumulative exposures to 'all fibre size indices, including fibres <5 um in length, were highly statistically significant predictors of lung cancer or asbestosis mortality.' (Stayner, Kuempel et al. 2008).

97.12. "Together, many characteristics contribute to EMP toxicity, such as biological persistence, inter-tissue migration, or *in vivo* comminution (splitting of bundles into elongate fragments or fibers). Interactions of EMP at the biological interface can trigger intracellular multiprotein complexes associated with inflammation.

97.13. "A number of studies (Goodglick and Kane 1990, Dodson, Atkinson et al. 2003, Ji, Wang et al. 2012) report an association between fiber length, width, and disease in laboratory animals and in exposed human populations. However, the methods, definitions, and protocols used to measure and count fibers in environmental samples are not independent of the specific analyst or microscope used to character exposures. (Rooker, Vaughan et al. 1982).

97.14. "Although shorter particles are generally more rapidly cleared than longer ones, at a steady state of exposure, short EMPs can accumulate, presenting a persistent and much larger bioactive surface area than the commonly recorded longer fibers. (Lehnert, Valdez et al. 1989).

97.15. "When comprehensive dose characterization has been available, biologically active EMPs, also known as censored EMPs (i.e., <5 μm in length), are often implicated as contributing

to disease. These EMPs have been frequently removed from the exposure analysis due to the limitations of optical microscopy. Further, our understanding of disease in relation to exposure (exposure-response analysis) is severely limited. The presence of elongate amphibole and serpentine minerals in some talc deposits have been known for many years (Kleinfeld, Messite et al. 1967, Rohl and Langer 1974, NIOSH 1980), yet analytical methods restricted by available technology (Rooker, Vaughan et al. 1982, Kenny, Rood et al. 1987) and developed for other purposes, have been adopted as tools for the scientific characterization of toxicological response and risk assessment in both occupational and non-occupational epidemiologic studies. This has severely limited our understanding of how exposure to EMPs of various size and characteristics contribute to asbestos-related disease (Stayner, Kuempel et al. 2008) [figure omitted].

97.16. "Thus, for the purpose of evaluating the presence of asbestos in talc intended for use in cosmetics and talc-containing cosmetics, measurement and characterization of EMPs should be more inclusive in order to consider biologically relevant physical-chemical characteristics as they relate to biological actions of the offending mineral particles." Appendices to White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc (p. 42-49).

98. According to Appendix F of the White Paper, titled "Testing Issues," "Some researchers have suggested that populations of amphibole asbestos fibers can be differentiated from non-asbestiform particles or cleavage fragments based on population width distributions reflecting differing tendencies in particle attrition among the two growth habits (Blount 1991; Van Orden et al. 2008, 2009; Harper et al. 2008). General guidelines for differentiation based on dimensions do not exist, although there are minima for length and aspect ratio for asbestos counting in published standards. The strict application of length and aspect ratio as measures to differentiate asbestiform

and non-asbestiform particles remains debated in the scientific literature. Thus, IWGACP is not in favor of using dimensional criteria to differentiate asbestiform and non-asbestiform particles in talc and cosmetics." Appendices to White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc (p. 71).

99. The significance of asbestiform versus nonasbestiform fibers was discussed by the pharmaceutical firm Pfizer, Inc. in 1977. Commenting on statements by the talc firm, R.T. Vanderbilt Co., Inc., Pfizer's official J.P. Bartels wrote in a memo, "Vanderbilt Talc Letter," "Tremolite then has always been classified as a form of asbestos." (p. 3).

99.1. Pfizer's Mr. Bartels stated, "[R.T. Vanderbilt] launched a massive effort to block the [OSHA] standard and later to overturn it. Initially their thrust was that the amphiboles were not asbestos and should not be included in the asbestos standard. Later they took the position that the five amphiboles involved, especially tremolite, existed in both 'asbestiform' and 'non-asbestiform' varieties and that Vanderbilt talc contained the non-harmful variety. Although their position has never been supported by any scientist of renown or any other talc company, Vanderbilt has remained adamant in their defense of it." Booker-MTI001061.

99.2. Pfizer's Mr. Bartels further stated, "Johns-Manville, another major talc producer, with considerable expertise in asbestos took a radically different approach. On September 30, 1974, they issued a letter stating that their Grantham talcs contained amphiboles of asbestos and placed asbestos warning labels on their talc packages. In June 1976, they officially shut down their Grantham talc operation in Death Valley and went out of business.

99.3. "Cyprus Mines and Engelhard have issued weak statements claiming that their products do not contain any asbestiform minerals." Booker-MTI001062.

100. In a Cyprus Ore Reserve Evaluation "Preliminary Summary," R.C. Munro stated,

100.1. "Fibrous minerals – tremolite and actinolite are ubiquitous in several zones of the Vermont mines. The potential problems involved with fibre in dumps, and to some degree in products, must be carefully evaluated." IMERYS 416201.

100.2. Discussing impurities, Munro further stated, "Actinolite: can be present (needles and blades) in most of the deposits (2*), generally in well known locations (close to walls or waste contacts, in the chloritic fault zones, in pinched zones of deposits). The miners know these zones and seem to master the problem (what for contractors?), but it is impossible to get rid of accidental traces." IMERYS 416215.

101. In an interoffice memo from Cyprus Mines dated March 25, 1992, R. C. Munro, under the heading "Tremolite," stated:

101.1. "The other serious mineralogical contaminant in the talc ores of Vermont is the fibrous variety of the amphibole minerals, tremolite and actinolite (hydrous calcium iron-magnesium silicates) which have been classified as asbestiform minerals by OSHA and EPA. OSHA was expected to de-classify non-fibrous (blocky) tremolite on February 29, but has not yet announced their decision.

101.2. "As a result, all tremolite, the fibrous varieties of al all amphiboles and chrysotile asbestos in talc ores are a source of great concern to all talc producers and especially to marketers of cosmetic products.

101.3. "Cyprus claims that there are not fibres in their cosmetic talc products and they work rigorously to ensure this. However, a recent paper published by Rutgers University worker, Alice Blount, suggests the presence of fibre in several cosmetic talcs, some of which might have been from Cyprus West Windsor material, which is a source of great concern to Cyprus management and potentially to their principal customer, Johnson & Johnson. Talc de Luzenac

personnel are well aware of the situation and Phillipe Moreau is currently quietly working to identify the reality and the magnitude of the problem.

101.4. "Vermont talcs are derived from altered serpentine - a natural host for asbestiform minerals. There is certainly visible tremolite and actinolite in specific zones of the Vermont deposits -fibrous tremolite was identified by the writer in exposures and cores at the East Argonaut and Black Bear mines. Cyprus staff report past tremolite from the Hammondsville and Clifton deposits.

101.5. "Tremolite in these deposits is encountered in the contact zones between the talc and the surrounding schist; in 'grey talcs' in the vicinity of the contacts; and associated with the chlorite/amphibole waste zones within the talc ores that are locally termed "cinders." Cyprus maintains a selective mining program in Vermont that is directed toward exclusion of all of these potentially fibre-bearing zones from the ores sent to the mills, and those suspect tonnages, including the associated talc, are left in the pit walls or sent to waste piles." IMERYS 219721.

102. In response to the position taken by some asbestos testing laboratory scientists that, "there is a toxicological difference between asbestos structures which formed as fiber crystals and fibers which formed by cleavage plane separation" (p. 11), the Environmental Protection Agency (EPA) Region 9 stated on April 20, 2006,

102.1. "It is the position of EPA, the U.S. Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry (ATSDR) and National Institute for Occupational Safety and Health (NIOSH), and the American Thoracic Society, among others, that microscopic structures of amphibole and serpentine minerals that are asbestiform and meet the size definition of PCM fibers, should be counted as asbestos, regardless of the manner by which they were formed.

102.2. "There are four reasons why the health agencies have taken this position: (1) The epidemiologic and health studies underlying EPA, and California EPA, cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, but were unable to distinguish between the two, (2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that "it is prudent at this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer, (3) No well-designed animal or human epidemiological studies have been conducted to date to test the hypothesis that cleavage fragments with the same dimensions of a fiber are benign, or that the human body makes any distinction, and studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts, (4) There are no routine air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and the ISO which differentiate between cleavage fragments and crystalline fibers." (p. 11) (footnotes omitted).

103. In my opinion, the safety of nonasbestiform amphibole or cleavage fragments was and has not been established.

104. In my opinion, determination by a laboratory that certain amphibole particles were nonasbestiform in nature does not mean the safety of those nonasbestiform amphiboles was substantiated.

105. In my opinion, the controversies and/or complexities surrounding: 1) the definition of asbestos; 2) what was excluded from the definition of asbestos; 3) the geologic relationship between asbestos and talc; 4) the difficulty of laboratory tests to characterize individual amphibole fibers as asbestiform or non-asbestiform; 5) whether cleavage fragments of similar dimensions to asbestiform fibers pose similar risks; 6) the difficulties distinguishing between asbestiform and

cleavage fragments as discussed below; 7) the limitations of detection by various laboratory measurements; 8) epidemiological results; 9) the inability over the decades of FDA to arrive at a definitive testing method for asbestos in talc; 10) the significance of talc fibers; and 11) the extent and routes of exposure, reinforce the conclusion that the safety of the product had not been established.

106. In my opinion, unable to substantiate the safety of their talcum powder products, JNJ was required to place the following conspicuous statement on the principal display panel: "Warning-The safety of this product has not been determined." 21 CFR §740.10.

IV. IN LIGHT OF LABORATORY TEST FINDINGS CONDUCTED BY, PROVIDED TO, OR MADE AVAILABLE TO JNJ, BEGINNING IN AT LEAST THE EARLY 1970S, JNJ COULD NOT SUBSTANTIATE THE SAFETY OF ITS TALCUM POWDER PRODUCTS AND SHOULD HAVE NOT SOLD ITS PRODUCTS

107. JNJ's corporate representative, Dr. John Hopkins, testified:

> Q. And [JNJ] has always told the public that there's never been a single fiber of asbestos in any of its talc for Johnson's Baby Powder or Shower to Shower, correct?
>
> A. Yes.
>
> Q. It told that to customers, nurses, doctors and regulators and hospitals, correct?
>
> A. Yes.[34]

107.1. Dr. Hopkins further testified:

> Q. [JNJ] agrees that if the baby powder has asbestos, it should be withdrawn from the market immediately, correct?
>
> A. It wouldn't be sold in the first place.
>
> . . .
>
> Q. And [JNJ] agrees with that, the acceptable level of asbestos in cosmetic talc [is] zero, right?

[34] Trial Testimony of Dr. John Hopkins in *Barden v. Brenntag North America, et. al*, MID-L-0932-17AS, July 22, 2019, at p. 43.

A. Yes.[35]

A. From the 1950s through the 2000s, JNJ received and acknowledged reports from affiliated and non-affiliated laboratories identifying or suspecting the presence of naturally occurring mineral silicate fibers of the serpentine and amphibole series including, but not limited to, tremolite fibers, actinolite fibers, anthophyllite fibers, amphibole asbestos, chrysotile (serpentine asbestos), fibrous talc and non-asbestiform amphibole in talc sample

108. JNJ's corporate representative, Dr. John Hopkins, and Imerys' corporate representative, Julie Pier, confirmed that from the 1950s through the 2000s, JNJ received and acknowledged reports from affiliated and non-affiliated laboratories identifying or suspecting the presence of naturally occurring mineral silicate fibers of the serpentine and amphibole series including, but not limited to, tremolite fibers, amphibole asbestos, chrysotile (serpentine asbestos), fibrous talc and non-asbestiform amphibole in talc samples.[36]

109. I have reviewed Exhibit D-1-A to Dr. John Hopkins' corporate representative deposition and Dr. Hopkins' deposition testimony about JNJ's response to the reports to JNJ of talc samples containing naturally occurring mineral silicate fiekutabers of the serpentine and amphibole series.[37] In his corporate representative deposition testimony, Dr. Hopkins confirmed that many of the reports JNJ received of naturally occurring mineral silicate fibers of the serpentine and amphibole series met the company's definition of asbestos.[38]

110. A May 10, 1971, report to JNJ from Colorado School of Mines identified: "Report results: 'Free nontalc needles' .6%. 'Free talc needles' 2.21%". JNJ 000294462 (J&J-255). In a May 14, 1971, internal memorandum, JNJ stated, "The attached letter shows the particle size-shape consists

[35] *Id.* at p. 198.
[36] Hopkins Dep. Ex. D-1-A; Hopkins Dep. Ex. 28; Pier Dep. Ex. 47; Deposition of Julie Pier, September 12-13, 2018.
[37] Hopkins Dep. Ex. D-1-A; Deposition of John Hopkins, Ph.D., October 17, 2018. *See also* Trial Testimony of Dr. John Hopkins in *Barden v. Brenntag North America, et. al*, MID-L-0932-17AS, July 22, 2019, at pp. 38-39 ("Q. Alright. Johnson & Johnson understood that it would be very, very bad for business and J&J's representation if it ever came out that baby powder or any of its talc products ever contained asbestos, correct? A. If the baby powder did contain asbestos, it would be bad for business, if it did, yes.").
[38] Hopkins Dep., October 17, 2018, 1070:3-22; Hopkins Dep. Ex. 27; Hopkins Dep. Ex. D-1-A.

of a production batch of our product produced in December, 1970." JNJ 000294462 (Ex. J&J-255). The internal memorandum concluded, "We consider the free non-talc needles but a trace, both on a count and area basis. Those particles are tremolite." JNJ 000294462 (Ex. J&J-255).

111. A JNJ memorandum dated July 29, 1971, stated, "The talc used in JOHNSON'S Baby Powder is obtained from a selected mine in Vermont where the ore consists mainly of platy talc with only trace amounts of fibrous minerals (tremolite/actinolite)." The memorandum continues, "The resulting talc has been shown by three independent consulting laboratories* [Colorado School of Mines Research Institute, McCrone Associates, Inc., and Dartmouth College Geology Department] to contain negligible traces of fibrous minerals and no chrysotile fibers." JNJMX88__000004646 (Ex. J&J-19).

112. A November 10, 1971, letter to Johnson & Johnson from Dr. Arthur M. Langer at Mount Sinai School of Medicine stated, "We have also analyzed one of your talc samples in some detail. In addition to the normal platy talc present, we have observed many 'fibrous talcs' as well." Dr. Langer continued, "We also observed trace amounts of chrysotile asbestos only when the talc was sonified and markedly dispersed. The amounts of chrysotile are relatively small, occurring in amounts, we estimate, at less than .01%." JNJTALC000292656.

113. An internal JNJ memorandum dated September 26, 1972, discussed the results of testing performed on Johnson and Johnson's product by FDA consultant Dr. S. Lewin on August 3, 1972 and September 21, 1972. The results showed, "J&J Medicated Powder sample: 4% tremolite," "Johnson's Baby Powder sample: 2% chrysotile," another "Johnson's Baby Powder sample: 3% chrysotile," "J&J Shower to Shower samples: 2% chrysotile" in 3 samples and "5% +/- 2%" in a 4th sample." JNJ000232996 (J&J-31)[39].

[39] S*ee also* Ex. J&J-28 (August 3, 1972 report).

114. An October 1972 internal JNJ handwritten note stated, "There are trace quantities present confirmed both by McCrone & Bill Ashton. Levels are extremely low but occasionally can be detected optically. This is not new." JNJAZ55_000004156 (J&J-26).

115. In 1972, University of Minnesota Space Science Center received "specimens of powdered talc" from "[JNJ] and from McCrone Associates. Analysis of these samples using the scanning electron microscope was requested in order to determine the possible content of fibrous chrysotile asbestos contained in the talc samples. The University of Minnesota reported "Numerous fibrous structures were observed during this examination of both the original Lewin material [the samples from McCrone] and the Shower to Shower material supplied by [JNJ]." Under the section titled "Transmission Electron Microscopy," the testing found "A large number of grids were examined and numerous examples of fibrous material were seen. Of the large number of grids examined, three examples of fibers which upon examination by electron diffraction could be classified as likely candidates for chrysotile asbestos in the [S]hower to [S]hower material and one example was found in the Lewin material," and "[i]n Figures 17a and 18a, electron micrographs of the transmission type show the typical stranded appearance of chrysotile asbestos." The University of Minnesota concluded, "It is felt therefore that chrysotile asbestos does exist in the specimens of [S]hower to [S]hower and Lewin supplied to this laboratory." JOJO-MA2546-01282 (J&J-33). The University of Minnesota's Thomas Hutchinson provided images of "Chrysotile Fibers Embedded in Talc Particles," and handwritten notes that stated, "Five fibrous particles were found which gave electron diffraction patterns unmistakably chrysotile asbestos" and "'Shower to Shower' . . . Three clear examples were found of serpentine material and which gave perfect chrysotile patterns." JOJO-MA2546-00138.

116. An internal JNJ memorandum dated April 19, 1973 titled "Dispersion Staining Examination of Retained Samples of Johnson's Baby Powder" stated, "Twenty-five samples of Johnson's Baby Powder representing retained samples from both ESDP and Chicago facilities were examined microscopically by the Dispersion-Staining technique for the presence of tremolite. Four of these samples are suspected of containing tremolite based on the finding of one or two 'fibers' per sample which satisfy the color/morphology criteria." JNJ 000245155 (J&J-296).

117. An internal JNJ memorandum dated April 26, 1973 stated: "It is our joint conclusion that we should not rely on the 'Clean Mine' approach as a protective device for Baby Powder in the current Asbestos or Asbestos-Form controversy. We believe this mine to be very clean; however, we are also confident that fiber forming or fiber type minerals could be found. The usefulness of the 'Clean Mine' approach for asbestos only is over." The memorandum went on, "Our Baby Powder contains talc fragments classifiable as fiber. Occasionally sub-trace quantities of tremolite or actinolite are identifiable (Optical Microscope) and these might be classified as asbestos fiber." The memorandum further "cautioned" that "no final product will ever be made which will be totally free from respirable particles." JNJMX68_000013464 (J&J-44).

118. An April 27, 1973 internal JNJ memorandum titled "Microscopic Examination of Johnson's Baby Powder" stated, "Petrographic optical microscopy revealed 'trace' amounts of amphibole in each of the above samples. Based on the number of particles scanned, we estimate 'trace' amounts to be .001 to .01% by weight." JNJMX68_000010608 (J&J-335).

119. A May 8, 1973 internal "Personal" memorandum from JNJ's William Ashton stated, "Baby Powder lots 108T & 109T were alleged to contain asbestiforms by Lewin. . .. The first showing of actinolite we know about is October 1972." JNJ 000301719 (J&J-368).

120. An internal JNJ memorandum dated May 16, 1973, titled "Proposed Specs for Analyzing Talc" stated, "'Preconcentration of Asbestos': "This technique has not been written up yet, but evidently when applied to Vermont talc, 0.05% of tremolite-type is found. The limitation of this method is that it may be too sensitive." JNJ 000232679.

121. An August 27, 1973 internal JNJ memorandum acknowledged that the "Dutch Consumer Organization" analyzed Johnson's Baby Powder and "detected asbestos-content of 1.59%." Johnson & Johnson noted that the Organization's definition of asbestos "could cause some errors," and "At this moment they are analyzing our powder again, because we remarked that our powder was free of asbestos. However, when they stick to the same method and definition they might trace asbestos again, and . . .. publicize the results." JNJAZ55_000006341 (J&J-299). A December 13, 1973 internal JNJ memorandum titled "asbestos in baby powder" stated, "On our request they have tested another sample and the result of this second test was 0.3% . . . " JNJAZ55_000006532.

122. A December 27, 1973 report prepared for JNJ by Colorado School of Mines titled "A Procedure to Examine Talc for the Presence of Chrysotile and Tremolite-Actinolite Fibers" stated, "Since developing the procedure, it has been applied to various talc samples examined for chrysotile and/or tremolite, as follows: A memorandum report dated April 2, 1973 [to JNJ] on the examination of four talc samples identified tremolite at levels of less than 20 ppm in one sample, and chrysotile at levels of less than 7 ppm in three samples. A letter report dated December 21, 1973 [to JNJ] on the examination of Italian and Vermont talc identified chrysotile at a level of less than 10 ppm in the Vermont sample." 57-0198 (J&J-263).

123. In March 1974, Dartmouth College sent a "Confidential" memorandum to Johnson & Johnson subsidiary Windsor Minerals Inc. titled "Analysis of Talc Products and Ores for Asbestiform Amphiboles." Dartmouth stated, "The purpose of this study is to develop methods for

measuring the concentration of asbestiform amphiboles in fine grained talc products and talc ores," and "For the reasons described above, a concentration technique is mandatory because it brings the amphiboles into a reasonable concentration range for optical or other methods of analysis." Dartmouth continued, "Talc ore and talc product, provided by V. Zeitz of Windsor Minerals, were run through this procedure." The memorandum concluded, "Conclusions: '(2) The ore sample contains 2300 ppm actinolite, and the talc product contains [approx.] 170ppm actinolite. (3) Actinolite is the dominant fiberform amphibole in the ore and talc product provided by Windsor Minerals. Small amounts of anthophyllite may be present.'" Further, "Plate 2" noted, "the length-striated character of actinolite; this is characteristic;" and "Plate 7" noted "Actinolite, talc, chromite, and a large anthophyllite fiber." JNJNL61_000029411 (J&J-58).

124. A May 8, 1974, report from JNJ subsidiary Windsor Minerals Company titled "Examination of Talc Ores and Products: Beneficiation Processes," examined McCrone Associates' testing of "6 samples of talc ores and talc products produced from these ores using the methods of light microscopy and transmission electron microscopy." The results included, "one fiber, probably tremolite" and "a few other fibrous or rod-shaped particles" in Sample 66A-ore, "fibrous forms of talc" in Sample 66U-ore, "one very small fiber" that "resembled chrysotile" in Sample 66U-product, "eight chrysotile fibers" in Sample 66AC-ore, "fibrous talc" and "one chrysotile fiber" in Sample 66AC-product. JNJ 000326107 (J&J-66).

125. On November 5, 1975, JNJ's testing agency McCrone Associates, Inc. sent a letter to Johnson & Johnson's subsidiary Windsor Materials Company "supplement[ing their] report of 1 July 1975 on a series of talc ore samples which we have analyzed for you." JNJNL6 _000079335 (J&J-97).[40] McCrone stated, "Table 1 shows the actual fiber counts . . .. Some of them seem rather

[40] S*ee* also JNJMX68_000012745 (J&J-89).

high, one had 10 and one had 9 amphiboles. Most of these come in bundles of 1, 2, or 3 fibers with anywhere from 2-5 amphiboles in a bundle." The attached "Table 1" reported "Fibers of Asbestos" in 10 samples. JNJNL61_000079335 (J&J-97).

126. On March 16, 1976, Johnson & Johnson sent "two nine ounce bottles of our Baby Powder" to Colorado School of Mines for testing. Handwritten notes dated July 5, 1976, stated, "Optical Mic shows small (1%?) amounts of amphibole needles." JNJ 000064762 (J&J-303).

127. An April 23, 1998, letter from Rutgers Professor Alice M. Blount, Ph.D. advised Johnson & Johnson that "as [she] told [JNJ]," her 1991 paper titled "Amphibole Content of Cosmetic and Pharmaceutical Talcs" identified JNJ's Baby Powder (Vermont Talc) as having "trace amounts of asbestos." J&J-0049150.[41]

128. On February 24, 2004, JNJ was faxed a report titled "Quantitative Analysis Report Asbestos in Bulk Material" describing results from a January 5, 2004, Transmission Electron Microscopy test of a Johnson's Baby Powder sample performed by Forensic Analytical. The "Analytical Results" found 3.8% anthophyllite asbestos in the Johnson's Baby Powder sample, equating to an "Asbestos Weight Percent" of .20%. JNJ 000375389.[42]

129. A 2013 JNJ "Draft" "Copy for Safety and Care Commitment Website" describing the company's "Use of Cosmetic Talc in Personal Care Products" was edited internally from "Our talc-based consumer products have always been asbestos free" to "Our talc-based products are asbestos free," noting that "we cannot say 'always.'" JNJTALC000067661.

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[41] *See also* Blount, A.M., *Amphibole Content of Cosmetic and Pharmaceutical Talcs*, Environmental Health Perspective, Vol. 94, at pp. 225-230 (1991).

[42] *See also* IMERYS299277 (March 22, 2004, email from Julie Pier stating, "Johnson & Johnson called us frantically, because some outside lab apparently found asbestos in off-the-shelf baby powder. . .. [I]t prompted J&J to ask us where all the data was on their product. I was supposed to be doing quarterly samples by TEM, but they were all in the backlog. Since 2001. Oops . . .").

130. In September 2018, FDA awarded AMA Analytical Services, Inc. "a one-year contract to test talc-containing cosmetics for the presence of asbestos fibers."[43] "AMA used Polarized Light Microscopy (PLM) and Transmission Electron Microscopy (TEM) to detect and quantify mineral particles suspected of being a form of asbestos."[44] "As part of this testing, two samples of Johnson's Baby Powder were tested: one sample from lot #22318RB was found to be positive for asbestos; a second Johnson's Baby Powder sample, lot #00918RA, tested negative for asbestos."[45] Specifically, "FDA testing [ ] found that [the sample from lot #22318RB] contains chrysotile fibers, a type of asbestos" and "a few talc fibers."[46]

131. On October 16, 2019, FDA advised JNJ that "Asbestos is a poisonous and/or deleterious substance, and, therefore, Johnson's Baby Powder Batch #22318RB is adulterated within the

[43] https://www.fda.gov/food/cfsan-constituent-updates/fda-releases-data-agencys-year-long-sampling-assignment-test-talc-containing-cosmetic-products. During the February 4, 2020 FDA "Public Meeting: Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc," FDA's Dr. Linda Katz acknowledged, "The manufacturers are responsible for making sure that the cosmetics that they market are safe for their intended conditions of use. They may do testing, and whatever testing they decide to do is up to them. We are not specific as to how these products must be tested." *See* Transcript of the FDA's Public Meeting, available at https://www.fda.gov/media/136305/download?attachment, at p. 12. Dr. Katz noted that FDA became aware of issues with testing "going back to the 1960s and '70s" and "began to grapple with what would be the best approach and proposed a mandatory optical microscopy method. But at the same time, in around 1976, the [CTFA] also began developing a new method. And that method was referred to as the CTFA Method J4-1. The method was actually published in the 'Asbestiform Amphibole Minerals in Cosmetic Talc.' And this method became the standard that industry used to assess for talc that was being used in cosmetic products. That basically this is a method that uses Polarized Light Microscopy only if the X-ray Diffraction is positive. . . . But that in terms of being able to identify chrysotile fibers, that its sensitivity is not really very good." *Id.* at pp. 14-15. Dr. Katz further stated that FDA "did not have capabilities to do the testing ourself," and "FDA has still no established labs to conduct this testing." *Id*. at p. 17. FDA has retained contract labs to conduct testing on limited occasions. *See* Dr. Lewin testing in 1972 (Ex. J&J-31, Ex. J&J-28); Sperry Rand confirmatory testing in 1972 (Ex. J&J-29); 2009-2010 AMA testing of 34 samples ("FDA Summary of Results from Testing of Official Samples of Talc-Containing Cosmetics of Asbestiform Fibers by AMA Laboratories During 2009-2010," available at https://www.fda.gov/media/122418/download?attachment); AMA 2019 testing (AMA Certificate of Analysis, available at: https://www.fda.gov/media/131989/download).

[44] https://www.fda.gov/food/cfsan-constituent-updates/fda-releases-data-agencys-year-long-sampling-assignment-test-talc-containing-cosmetic-products.

[45] https://www.fda.gov/news-events/press-announcements/baby-powder-manufacturer-voluntarily-recalls-products-asbestos.

[46] *See* AMA Certificate of Analysis, found at: https://www.fda.gov/media/131989/download; *see also* https://www.fda.gov/news-events/press-announcements/baby-powder-manufacturer-voluntarily-recalls-products-asbestos.

meaning of Section 601(a) of the Federal Food, Drug, and Cosmetics Act." JNJTALC001281991. On October 18, 2019, JNJ voluntarily recalled "Lot #22318RB of Johnson's Baby Powder."[47]

132. JNJ provided FDA with an "Investigation Final Report" regarding Lot #22318RB. According to JNJ, "the resulting investigation has determined that [Johnson's Baby Powder] does not contain chrysotile based on the totality of the evidence," and "the most probable causes are lab contamination error and/or chrysotile mis-identification." JNJTALC001284148. In a prior draft of JNJ's report, JNJ internally suggested removing language that chrysotile asbestos has never been "detected" ("I know this is accurate but since Imerys detected but later confirmed it was an environmental contaminate should we choose the word like confirmed?) and questioned why TEM was not used in sampling ("But no TEM? Would there be a rationale why not?"; "Do we really have a good answer regarding the lack of TEM done by Imerys?"; "How do we resolve that less TEM is done or am I wrong that it is and doesn't matter?"). JNJTALC001298411.

133. AMA's Andreas Saldivar confirmed AMA's results in his March 19, 2020, deposition:

> "Q. Here's my question: For the results you turned over to the U.S.F.D.A., as a result of this·contract of some 50 samples, whether or not those were -- those results reported in non-detect or a positive finding of asbestos, does AMA stand behind all of its results?
>
> A. Yes.
>
> MR. MASSENBURG:· Form.
>
> BY MR. PANATIER:
>
> Q. Okay. And did AMA follow all of the appropriate separation and analytical methodologies that it told the F.D.A. it would?
>
> A. We did, and we also followed all instructions from the F.D.A.
>
> Q. Okay. All right. In that respect, sir, did you turn over valid results to the F.D.A.?

[47] https://www.jnj.com/johnson-johnson-consumer-inc-to-voluntarily-recall-a-single-lot-of-johnsons-baby-powder-in-the-united-states.

A. We did.

Andreas Saldivar Dep., 129:2-17.

134. On May 19, 2020, JNJ "announced the discontinuation of talc-based baby powder in the United States and Canada."[48] Following this announcement, the House Subcommittee on Economic and Consumer Policy stated, "My Subcommittee's 14-month investigation revealed that [JNJ] knew for decades that its product contains asbestos, and the company fought to keep using a testing method that would never have allowed it to be detected."[49]

135. In addition, I have reviewed other documents describing JNJ conducting or learning about additional findings of naturally occurring mineral silicate fibers of the serpentine and amphibole series in talc samples.[50]

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[48] https://oversightdemocrats.house.gov/news/press-releases/oversight-subcommittee-s-year-long-investigation-leads-to-johnson-johnson.

[49] https://oversightdemocrats.house.gov/news/press-releases/oversight-subcommittee-s-year-long-investigation-leads-to-johnson-johnson.

[50] *See, e.g.*, JNJNL61_000000266 (July 13, 1966 internal Johnson & Johnson memorandum titled "Microscopic Examination Museum Baby Powder Samples, identifying "tremolite" and "fibrous talc"); JNJAZ55_000004563 (October 10, 1967 internal Johnson & Johnson memorandum reporting microscopic examination of three talc samples and finding "nonplaty talc" and "serpentine" non-talc particles in all three samples); JNJAZ55_000006090, J&J-15 (July 7, 1971 report from Colorado School of Mines on the "344-L Vermont talc product and the six monthly Vermont talc product samples, detecting minor amounts (below 1%) of "tremolite and actinolite."); JNJAZ55_000008893, J&J-257 (September 3, 1971 finding low percentages of "chrysotile" in Shower to Shower tested by McCrone); JNJAZ55_000005958, J&J-23 (October 12, 1971 McCrone analysis finding traces of chrysotile in one of the additives in Shower to Shower); JNJ 000248615, J&J-29 (August 24, 1972 Johnson & Johnson handwritten notes regarding "Talc/Asbestos Shower to Shower Talc," detailing Sperry Rand report of asbestos fibers detected in the Shower to Shower sample previously examined by Dr. Lewin."); JNJ000260833, J&J-34 (October 27, 1972 McCrone report to Johnson & Johnson with handwritten "Do not use this Report. Replaced by Another Version," which deleted references to specific amount of tremolite detected in talc samples); JNJNL61_000008084, J&J-100 (February 26, 1973 report from Colorado School of Mines titled "Mineralogical Examination of Five Talc Samples," finding "slight traces of tremolite-actinolite minerals," "a very minor amount of serpentine which may be chrysotile," and "possible serpentine fibers."); JNJMX68_000002666, J&J-65 (April 24, 1974 McCrone report of core samples taken from ore body and reporting chrysotile asbestos and fibrous tremolite when using transmission electron microscopy); J&J-74 (October 10, 1974 McCrone report of samples from Windsor Materials, finding one sample to "contain fibrous asbestiform material," and other samples to contain "chrysotile fibers"); JNJMX68_000012745, J&J-89 (July 1, 1975 McCrone report to Windsor Materials, finding "these samples do show some amphiboles at an extremely low level," and "We kept a running tabulation of the asbestos which we could positively identify . . . In no case did the asbestos content exceed medium."); JNJNL61_000064366, J&J-92 (September 9, 1975 Johnson & Johnson memorandum regarding Dr. Langer's analysis of talcum powder products, stating "He has identified the products by name and claims that he

has detected tremolite and anthophyllite in Johnson's Baby Powder."); J&J-0150033 (March 31, 1976 Johnson & Johnson internal memorandum regarding "meeting with Johnson & Johnson personnel and the Mt. Sinai School of Medicine," stating, "The Mt. Sinai group indicated that over the weekend the Selikoff group had been studying 6 new samples of talc and had reported that all of them contained minimal amounts of asbestos."); J&J-0043753 (November 14, 1978 letter regarding "Reducing the Number of ore Samples Collected for Analysis by McCrone Associates," and stating from "Mid-1975 to May 1978 . . . Three samples only contained asbestiform fibers, one in each of these samples, i.e., 2 amphiboles and 1 chrysotile fiber."); Ex. J&J-164 (February 9, 1979 report from George Lee's Group finding tremolite and actinolite in composite samples); J&J-0085506 (March 4, 1981 Johnson & Johnson internal memorandum analyzing Guang Dong talc and noting "Classification of the various components in this talc sample is as follows: . . . Approximately 1% tremolite. (US Health agencies will classify this component under asbestos fiber definition); Ex. J&J-305 (January 12, 1984 McCrone report analyzing "for asbestos in the talc sample . . . identified as 'Talc Powder – Superior Grade EV' and finding that "Using polarized light microscopy with dispersion staining, it was determined that the sample contains 2 to 3% by weight tremolite-actinolite. The tremolite-actinolite in the sample is considered to be asbestos by current government regulations; however it appears to be cleavage fragments of the massive form rather than true asbestiform."); Ex. J&J-177 (May 15, 1984 report from Mine Safety and Health Administration documenting asbestos at a mill used to supply Johnson & Johnson talc); J&J-0145303 (February 26, 1985 "Analytical Request and Report" submitted to Johnson & Johnson identifying sample of 100T lot of cosmetic grade Chinese talc to be "asbestiforms positive" using "Microscopy."); J&J-0034630 (August 22, 1985 McCrone report to Windsor Minerals, Inc. analyzing seven talc samples and finding "The presence of asbestos minerals was verified by selected area electron diffraction (SAED), energy dispersive x-ray analysis (EDX) and by morphology," and reporting "chrysotile asbestos" in 2 of the 7 talc samples); Ex. J&J-182 (April 29, 1986 McCrone report to Windsor Minerals analyzing "three (3) talc samples for asbestos analysis," and finding that "Examinations by transmission electron microscopy resulted in the detection of trace amounts of chrysotile asbestos in the samples."); Ex. J&J-260 (March 14, 1988 letter to Johnson & Johnson from R.J. Lee analyzing "a talc sample using transmission electron microscopy to determine the serpentine and amphibole content," with analysis "confined to the fibrous forms," and concluding that "talc sample 879-57 Talc L contains approximately .0024% of chrysotile and .014% of fibrous tremolite."); J&J-0145151 (January 17, 1989 "Talc Analysis" of Talc Powder, 200 Mesh Quixia Shan Dong performed by ES Laboratories, Inc. for Johnson & Johnson's Baby Powder division using the "CTFA J4-1 Method," and finding "0.5%" in "Amphibole Group ['Tremolite, Actinolite, and Anthophyllite']" and "1.0%" in "Serpentine Group ['Chrysotile"']"); JNJNL_000006792 (Pier Dep. Ex. 36) (May 23, 1989 letter from RJ Lee Group to Johnson & Johnson regarding "detailed analytical electron microscopical analysis of [Sample 731-116]" and detecting "two chrysotile fibers in the area examined (10 grid squares)."); JNJ 000223449 (July 31, 1989 RJ Lee Group letter to Johnson & Johnson regarding "detailed analytical electron microscopical analysis of [Sample 731-120]" and detecting "three (3) chrysotile fibers in the area examined (10 grid squares)."); Ex. J&J-202 (March 25, 1992 report titled "Cyprus Ore Reserves-Arsenic and Tremolite" noting that "serious mineralogical contaminant in the talc ores of Vermont is the fibrous variety of the amphibole minerals, tremolite and actinolite (hydrous calcium iron-magnesium silicates) which have been classified as asbestiform minerals by OSHA and EPA."); Ex. J&J-327 (April 1, 1992 report titled "Cyprus Ore Reserve Evaluation Preliminary Summary" stating that "Fibrous minerals – tremolite and actinolite are ubiquitous in several zones of the Vermont mines."); J&J-0077385 (October 13, 1995 letter from RJ Lee Group to Johnson & Johnson finding "One tremolite particle" in the Johnson's Baby Powder sample tested); J&J-0021092 (August 25, 1997 report from State University of New York examining sample of Johnson's Baby Powder, and finding "Intermixed with the platy particles were long fibrous particles which had a chemical composition of talc. Several of the fibers observed were asbestiform in nature with diameters less than 5 micrometers and lengths greater than 10 micrometers. Some curved 'serpentine' fibers were found with similar composition."). *See also* The Analysis of Johnson & Johnson's Historical Product Containers and Imerys' Historical Railroad Car Samples from the 1960's to the Early 2000's for Amphibole Asbestos, 2nd Supplemental Report of William E. Longo, Ph.D. and Mark W. Rigler, Ph.D., February 1, 2019 ((providing results from PLM, ATEM and HLS testing of 72 historical talc samples from both the Italian (from 1960 to 1967) and Vermont talc mines (from the last 1960s, 1970s, 1980s, 1990s, and early 2000s): 57 Johnson & Johnson powder samples (including 34 from Johnson's Baby Powder, 23 from Johnson and Johnson's Shower to Shower containers), and 15 separate cosmetic talc samples from Imerys labeled "Railroad Car," and finding that 42 of the 57 historical Johnson & Johnson talc samples (73%) were positive for amphibole asbestos and possessed

136. I also reviewed trial testimony of Dr. Hopkins during which he detailed and confirmed various laboratory tests JNJ received of talc samples containing naturally occurring mineral silicate fibers of the serpentine and amphibole series.[51]

137. I have reviewed multiple JNJ documents describing talc samples in which no naturally occurring mineral silicate fibers of the serpentine and amphibole series were detected.[52] This is not surprising since, as detailed below, JNJ opposed testing methods that were too sensitive and implemented methods that had significant limits of detection.[53] I also recognize that on subsequent testing, or retesting or reinterpretation, findings changed.

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significant amounts of amphibole asbestos fibers/bundles per gram of talc, and 8 of the 15 Imerys "Railroad Car" samples (53%) were positive for asbestos); Trial Testimony of Matthew Sanchez, Ph.D. in *Ingham, et. al v. Johnson & Johnson, et. al*, Cause No. 1522-CC10417-01, June 27-28, 2018. In an email dated June 2, 2009, sent by Rio Tinto's Rhea Kincaid, Product Stewardship, distributed an attachment labeled "May Highlights – Product Stewardship/Regulatory Affairs." The document states, "Chinese authorities informed J&J that its internal testing confirmed asbestos in several talc body powders marketed in China including two products from J&J. However, four independent Chinese laboratories using similar test method to the Chinese authorities did not find any asbestos. J&J approached RTM for help on the issue. RTM provided initial support in identifying potential drawback of the test method used by the Chinese authorities. Chinese authorities invited J&J, the other concerned talc body powder companies, and the four independent Chinese laboratories whose asbestos test results were negative to discuss and resolve the test method discrepancies." IMERYS 309325-28.

[51] *See, e.g.*, Trial Testimony of Dr. John Hopkins in *Ingham, et. al v. Johnson & Johnson, et. al*, Cause No. 1522-CC10417-01, April 16, 2019, at pp. 5342-5365, 5371-5373; Trial Testimony of Dr. John Hopkins in *Barden v. Brenntag North America, et. al*, MID-L-0932-17AS, July 22, 2019, at pp. 118-119, 193-194 (regarding Dr. Langer's confirmation that his team found asbestos in Johnson's Baby Powder), at pp. 225-226 (regarding Colorado School of Mines May 1971 findings), at pp. 271-274 (regarding Dr. Langer's 1970s analysis of talc samples).

[52] *See, e.g.*, Exs. D-0263 to D-0732 (identifying non-detect results from 1990 to 1994); D-0916 to D-1919 (2005); D-1019, D-1029 (2009); D-1256 to D-1258 (2013); D-1447 to D-1471 (1973 to 1979).

[53] *See also* JNJMX68_000009139 (December 17, 1974 JNJ letter stating, "We believe it is critical for the C.T.F.A. to now recommend these methods to the F.D.A. before the art advances to more sophisticated techniques with higher levels of sensitization."); J&J-0084545 (February 18, JNJ letter regarding analytical testing methods stating, "I have also included our test method for the proposed Xray technique which was drawn up by Boots Ltd in conjunction with Dr. Pooley. We deliberately have not included a concentration technique as we felt it would not be in worldwide company interests to do this."); JNJ000242147 (November 24, 1976 Johnson & Johnson letter from William Ashton to George Lee discussing FDA's proposal request regarding "Separation of Asbestos in Foods, Drugs and Talc for Identification and Determination," recognizing that "As I have pointed out many times, there are many talcs on all markets which will be hard pressed in supporting purity claims when ultra sophisticated assay separation and isolation techniques are applied. Chances are that this FDA proposal will open up new problem areas with asbestos and talc minerals."); IMERYS446794 (April 4, 2002, email from Julie Pier discussing R.J. Lee's approach); IMERYS299322 (Pier Dep. Ex. 18) (March 1, 2004 emails between Julie Pier and Rich Zazenski detailing "J&J criteria" for testing and reporting "no asbestos").

138. I recognize that all laboratory tests have some limitations and can be "explained away." The opinions below are based on the totality of evidence JNJ and its affiliates accumulated over 50 years, not on any one laboratory test or set of tests.

139. In my opinion, based on the totality of evidence, JNJ's findings and notice of naturally occurring mineral silicate fibers of the serpentine and amphibole series including, but not limited to, tremolite fibers, actinolite fibers, anthophyllite fibers, amphibole asbestos, chrysotile (serpentine asbestos), fibrous talc and non-asbestiform amphibole in talc samples prohibited JNJ from selling JNJ talcum powder products because they contained poisonous and deleterious substances, which "***may*** render" the products "injurious to users under the conditions of use described in the labeling thereof or under such conditions of use as are customary or usual . . . ," and were therefore adulterated. 21 U.S.C. § 361 (emphasis added).

140. In my opinion, based on the totality of evidence, at a minimum, Johnson & Johnson's findings and notice of naturally occurring mineral silicate fibers of the serpentine and amphibole series including, but not limited to, tremolite fibers, actinolite fibers, anthophyllite fibers, amphibole asbestos, chrysotile (serpentine asbestos), fibrous talc and non-asbestiform amphibole in talc samples prohibited the company from determining that the safety of Johnson & Johnson talcum powder products had been substantiated.

V. THE DEFENDANTS DID NOT SUBSTANTIATE THE SAFETY OF THEIR PRODUCT IN LIGHT OF QUESTIONS RAISED BY SCIENTIFIC EPIDEMIOLOGICAL STUDIES AND REVIEWS CONCERNING THE SAFETY OF TALC

141. As noted above, according to industry standards, if there is evidence that there are reasonable grounds to suspect that the cosmetic product may pose harm for the proposed conditions of use, such products do not meet the industry standards for safety.

142. Further, as noted above, FDA regulations require that a cosmetic manufacturer has a

responsibility to substantiate the safety of their product or must warn consumers that the safety of their product has not been determined.

143. The safety of a cosmetic, as is the case for other FDA regulated products, needs to be determined "under such conditions of use that are customary or usual . . ."[54] Thus, it is not the safety of talc that is determinative, rather it is the safety of talc as it is in fact used. Thus safety needed to be substantiated for talcum powder products that come into contact with the perineum/genital area.

A. FDA's 2014 Citizen's Petition Response stated there was some evidence to suspect or question the safety of talcum powder products

144. In its 2014 response to the 1994[55] and 2008 Citizen's Petitions, the FDA stated, "epidemiologic data [] show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder. While the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as you are seeking."[56] Steven M. Musser, Ph.D., letter to Samuel S. Epstein, April 1, 2014.

145. The FDA's response continued, "While there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may

[54] Section 601 of the FD&C Act [21 U.S.C. 361].
[55] As I stated above, based on my recollection, I was not personally and substantially involved in talc matters while Commissioner. There were certain letters that were addressed to the Commissioner during that time period concerning talc.
[56] The FDA response reviewed data dating back to at least 1961 and performed an expanded literature search from 2008-2014.

elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers."

146. While I am a professor of Epidemiology and Biostatistics, I leave it to other experts to discuss in detail the strengths, weaknesses, and specifics of the scientific evidence. FDA's statement that "epidemiological data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder," while not supporting, in FDA's opinion, the petition's request for a "definitive" warning, demonstrates that the safety of talcum powder products was in question. Schedule 4 provides a summary of epidemiologic studies concerning the association of talcum powder products and ovarian cancer.

147. Searches of PubMed for "talc and ovarian cancer" and "body powders and ovarian cancer" from 01/01/2014-11/09/2023 demonstrates since the FDA response to the citizens petition in 2014 there are ten (10) publications of original data including meta-analyses, clinical studies, clinical trials, systematic reviews, and observational studies.[57]

148. I reviewed the abstracts from these 10 articles. From those, I selected all epidemiological studies, including cohort studies (1), and meta-analyses (5) relating to talcum powder usage and the risk of ovarian cancer.[58]

149. These epidemiological studies include:

a. A meta-analysis published by Berge et al. "resulted in a weak but statistically significant association between genital use of talc and ovarian cancer, which

[57] The searches yielded ten (10) articles and one (1) article respectively. Note that there is no "article type" or "filter" for pooled study. *See* below for listing of additional studies that this PubMed search did not identify with the above search criteria.

[58] The remaining four (4) include: 1) Leemans, et al.; and 2) Frost, et al. that are both related the use of talc with pleurodesis; 3) Rasmussen, et al., studies the association between pelvic inflammatory disease and ovarian cancer; and 4) Mundt, et al. is a systematic review that does not have a meta-analysis associated with it.

appears to be limited to serous carcinoma." However, the authors concluded: "Several aspects of our results, including the heterogeneity of results between case-control and cohort studies, and the lack of a dose-response with duration and frequency of use, however, do not support a causal interpretation of the association." Berge 2017.

b. Another meta-analysis published by Penninkilampi and Eslick found that "[any] perineal talc use was associated with increased risk of ovarian cancer (OR = 1.31; 95% CI = 1.24, 1.39). More than 3600 lifetime applications (OR = 1.42; 95% CI = 1.25, 1.61) were slightly more associated with ovarian cancer than <3600 (OR = 1.32; 95% CI = 1.15, 1.50). An association with ever use of talc was found in case-control studies (OR = 1.35; 95% CI = 1.27, 1.43), but not cohort studies (OR = 1.06; 95% CI = 0.90, 1.25). However, cohort studies found an association between talc use and invasive serous type ovarian cancer (OR = 1.25; 95% CI = 1.01, 1.55)." This is the most common type of ovarian epithelial cancer. Penninkilampi 2018.

c. Regarding a potential mechanism for the observed increased risk, Penninkilampi and Eslick state "[t]he mechanism by which perineal talc use may increase the risk of ovarian cancer is uncertain. It has been previously proposed that talc, as a foreign body, may ascend from the vagina through to the uterine tubes and instigate a chronic inflammatory response, which may predispose to the development of ovarian cancer. It is argued that cellular injury, oxidative stress, and local increase in inflammatory mediators such as cytokines and prostaglandins may be mutagenic and hence promote carcinogenesis. If chronic

inflammation due to ascending foreign body is indeed the mechanism by which talc use is associated with increased ovarian cancer risk, then these results fit the picture." *Id*.

d. Taher, et al. (2019) is a meta-analysis that showed a positive association between a perineal use of talc powder and ovarian cancer was found [OR: 1.28 (95% CI: 1.20-1.37)]. A significant risk was noted in Hispanics and Whites, in women applying talc to underwear, in pre-menopausal women and in post-menopausal women receiving hormonal therapy. A negative association was noted with tubal ligation.

e. Woolen, et al. (2022) studied women with frequent perineal talcum powder use and finding "[f]requent talcum powder use was associated with an elevated risk of ovarian cancer (adjusted pooled summary odds ratio 1.47 (95% CI 1.31, 1.65, P<0.0001). There was no evidence of bias and low heterogeneity (I2= 24%, P=0.22)."

f. Houghton, et al. (2014) is a cohort study[59] based on data from the Women's

[59] JNJ's "Facts About Talc" under "Explore the Science: Studies on Talc and Ovarian Cancer" describes three [or four depending on whether the Nurses' Health Study is broken down NHS (Gertig 2000) and NHSII (Gates 2010)] prospective studies published between 2000 and 2016 that considered an association between the perineal use of talc and ovarian cancer. (https://www.factsabouttalc.com/studies). These are the Nurse's Health Study (Gertig, 2000 and Gates 2010), the Women's Health Initiative (Houghton 2014) and The Sister Study (Gonzalez 2016). None of these three cohort studies found a significantly increased overall risk of ovarian cancer.

These studies cited their limitations:

The Nurses' Health Study authored by Gertig (2000) cites for example: a) "the questions on talcum powder use refer to ever use and we cannot determine the age at which women began using talc or the duration of use"; b) "our relatively short follow up period may be inadequate to detect an association if the latency for development of ovarian cancer is more than 15 years"; c) "although we controlled of tubal ligation history the tubal ligation question was asked as part of a question on contraception use: therefore, postmenopausal women who were not sexually active may not have responded to the question"; and d) "[t]he prevalence of talc use in our study is somewhat higher than that in other studies and may reflect the fact that we asked about frequency of ever use rather than current use."

Health Initiative. Perineal powder use was assessed at baseline by self-report regarding application to genitals, sanitary napkins, or diaphragms and duration of use." The authors found, "[e]ver use of perineal powder (hazard ratio [HR]adj = 1.06, 95% confidence interval [CI] = 0.87 to 1.28) was not associated with risk of

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The Nurses' Health Study authored by Gates (2010) cites for example: a) "although our analysis included a large number of epithelial cases, we had a limited number of cases with certain subtypes and there was incomplete data for a few exposures, in particular talc use and family history of ovarian cancer"; and b) "the incomplete data may have influenced the observed associations for these exposures". Of note, the Nurses' Health Study by Gates only obtained information about talc use at baseline ("information on frequency of genital talc use was collected in 1982.").

The Women's Health Initiative authored by Houghton (2014) cites for example: a) "our analysis includes a lack of information regarding oophorectomy after baseline, which would result in the inclusion of some women not at risk for ovarian cancer in the analytical cohort"; b) "we have information on duration of powder use but not frequency"; c) "those using powder prior to 1976 may have been potentially exposed to asbestos, a known carcinogen"; d) "the WHI queried general perineal powder use rather than talc powder use and we had no specific information regarding the content of talc in products used."

The Sister Study authored by Gonzalez (2016) cites for example: a) "An important limitation of our study is that we collected douching and talc information on individuals for the year prior to study entry and have not accounted for the latency of ovarian cancer, which is likely to be long"; and b) "[a]t baseline participants were asked about douching and talc use during the previous 12 months". Of note, the Sister Study had a median follow up period of 6.6 years.

Recent meta-analysis that included: a) cohort studies; b) case-control studies; or c) combine cohort and case-control studies, were done by Penninkilampi (2018), Berge (2018), Taher (2019), Woolen (2022).

In Penninkilampi meta-analysis (2018), for all cohort and case-control studies found "Any perineal talc use was associated with increased risk of ovarian cancer (OR = 1.31; 95% CI = 1.24, 1.39)." Subgroup analysis: Cohort studies for all ovarian cancer found an "(OR = 1.06; 95% CI = 0.90, 1.25). However, cohort studies found an association between talc use and invasive serous type ovarian cancer (OR = 1.25; 95% CI = 1.01, 1.55)."

In Berge meta-analysis (2018), the "main meta-analysis" for the combined cohort and case-controlled studies found "the summary relative risk (RR) for ever use of genital talc and ovarian cancer was 1.22 [95% confidence interval CI 1.13-1.30]. The stratified meta-analysis showed a RR for case–control studies was 1.26 (95% CI: 1.17–1.35) and for cohort studies was 1.02 (95% CI: 0.85–1.20)."

In Taher meta-analysis (2019), for the combined cohort and case-control studies, found "[a] positive association between perineal use of talc powder and ovarian cancer was found [OR: 1.28 (95% CI: 1.20-1.37)]." Subgroup analysis: cohort effect was 1.06 (0.90, 1.25).

In Woolen meta-analysis (2022), for the combined cohort and case-control studies, found "[f]requent talcum powder use was associated with an elevated risk of ovarian cancer (adjusted pooled summary odds ratio 1.47 (95% CI 1.31, 1.65, P<0.0001)."

A recent pooled analysis of the four large cohort studies by O'Brien (2021) found that "the estimated HR for frequent vs never use was 1.09 (95% CI, 0.97 to 1.23 and for long-term vs never use, the HR was 1.01 (95% CI, 0.82 to 1.25). However, the estimated HR for the association between ever use of powder in the genital area and ovarian cancer risk among women with a patent reproductive tract was 1.13 (95% CI, 1.01 to 1.26)."

> ovarian cancer compared with never use. Individually, ever use of powder on the genitals (HRadj = 1.12, 95% CI = 0.92 to 1.36), sanitary napkins (HRadj = 0.95, 95% CI = 0.76 to 1.20), or diaphragms (HRadj = 0.92, 95% CI = 0.68 to 1.23) was not associated with risk of ovarian cancer compared with never use, nor were there associations with increasing durations of use."

150. I am aware of several studies since 2014 that the PubMed search on 11/9/2023 did not identify. For completeness they are:

150.1. In a case-control and pooled study from Cramer et al., overall, "genital talc use was associated [with EOC] with an OR (95% CI) of 1.33 (1.16, 1.52) with a trend for increasing risk by talc years." The authors stated that "[t]hese observations provide a framework for talc carcinogenicity in EOC involving chronic inflammation. Cramer 2016.

150.2. Using four case-control studies, Wu et al., examined six "well-accepted" risk factors for invasive epithelial ovarian cancer, including talc use, among Hispanics, African-Americans, and non-Hispanic whites. The population attributable risk percentage (PAR%) estimate was "12.2% to 15.1% for using talc in the three groups." The combined OR with talc use was 1.46 (95% CI 1.27-1.69 (Wu 2015).

150.3. In a study of African American women from Schildkraut et al., "[g]enital powder was associated with an increased risk of [epithelial ovarian cancer] EOC (OR = 1.44; 95% CI, 1.11-1.86) and a dose-response relationship was found for duration of use and number of lifetime applications ($P < 0.05$)." The authors concluded that "[t]he results support that body powder is a modifiable risk factor for EOC among AA women."

150.4. Regarding mechanism, Schildkraut et al. stated that their results "are consistent with localized chronic inflammation in the ovary due to particulates that travel through a direct

transvaginal route. The dose-response observed for duration of genital powder use provides further evidence for the relationship between genital powder and overall EOC risk."

150.5. Davis, et al. (2021) is a meta-analysis using "data from five studies in the Ovarian Cancer in Women of African Ancestry consortium" and found "[e]ver use of genital powder was associated with higher odds of ovarian cancer among African-American women [OR = 1.22; 95% confidence interval (CI) = 0.97-1.53] and White women (OR = 1.36; 95% CI = 1.19-1.57). In African-American women, the positive association with risk was more pronounced among high-grade serous tumors (OR = 1.31; 95% CI = 1.01-1.71) than with all other histotypes (OR = 1.05; 95% CI = 0.75-1.47). In White women, a significant association was observed irrespective of histotype (OR = 1.33; 95% CI = 1.12-1.56 and OR = 1.38; 95% CI = 1.15-1.66, respectively)." Davis further concluded, "[w]hile genital powder use was more prevalent among African-American women, the associations between genital powder use and ovarian cancer risk were similar across race and did not materially vary by histotype."

150.6. O'Brien, et al. (2020) is a pooled study using data from the Nurses' Health Study. "Ovarian cancer incidence was 61 cases/100 000 person-years among ever users and 55 cases/100 000 person-years among never users (estimated risk difference at age 70 years, 0.09% [95% CI, -0.02% to 0.19%]; estimated HR, 1.08 [95% CI, 0.99 to 1.17]). The estimated HR for frequent vs never use was 1.09 (95% CI, 0.97 to 1.23) and for long-term vs never use, the HR was 1.01 (95% CI, 0.82 to 1.25)." The authors found further that "While the estimated HR for the association between ever use of powder in the genital area and ovarian cancer risk among women with a patent reproductive tract was 1.13 (95% CI, 1.01 to 1.26), the P value for interaction comparing women with vs without patent reproductive tracts was .15."

150.7. Gonzalez, et al. reported on data from the Sister Study looking at douching, talc

use, and risk of ovarian cancer. The authors found, "[t]here was little association between baseline perineal talc use and subsequent ovarian cancer (HR: 0.73, CI: 0.44, 1.2). Douching was more common among talc users (odds ratio: 2.1, CI: 2.0, 2.3), and douching at baseline was associated with increased subsequent risk of ovarian cancer (HR: 1.8, CI: 1.2, 2.8)." The authors concluded, "[d]ouching but not talc use was associated with increased risk of ovarian cancer in the Sister Study."

151. In my opinion, based on FDA's analysis to the citizens petitions and the totality of the medical literature since FDA's 2014 petition response, there is scientific evidence to suspect or question the safety of talcum powder products.

B. The International Association for Research on Cancer (IARC) concluded that there was evidence of talcum powder's carcinogenicity.

152. In 2010, IARC published Monograph 93, which found that "[t]he relative risks for ovarian cancer among users of body powder (versus non-users) were homogenous across this relatively diverse set of eight studies, each of which indicated a 30–60% increase in risk . . . Perineal use of talc-based body powder *is possibly carcinogenic to humans (Group 2B)*." "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 93," 2010.4F[60] This monograph specifically addresses the safety of talc not containing asbestiform fibers.

153. In regard to asbestos, talc containing asbestos, and talc containing asbestiform fibers (fibrous talc), IARC published Monograph 100c, which found that, "[t]here is *sufficient evidence* in humans for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite). Asbestos causes mesothelioma and cancer of the lung, larynx, and ovary . . . There is *sufficient evidence* in experimental animals for the carcinogenicity

[60] IARC looked at data dating from at least 1933.

of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite). All forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite) are *carcinogenic to humans (Group 1)*." "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 100c," 2012. "The conclusions reached in this *Monograph* about asbestos and its carcinogenic risks apply to these six types of fibres wherever they are found, and that includes talc containing asbestiform fibres."[61]

C. Defendants failed to substantiate the safety of their talcum powder products

154. In my opinion, in light of a) the FDA's 2014 petition response acknowledging that there remains some evidence to suspect or question the safety of talcum powder products, b) the totality of the medical literature since 2014 that continues to raise safety questions; and c) IARC's classification, defendants failed to substantiate the safety of their talcum powder products.

VI. ALTHOUGH CONTROVERSIES AND COMPLEXITIES EXISTED, JNJ DEFENDED ITS PRODUCT DESPITE SIGNIFICANT QUESTIONS REGARDING ITS SAFETY AND PUT THE PUBLIC AT RISK

A. JNJ recognized iconic nature of their product

155. On July 22, 2019, JNJ's corporate representative John Hopkins testified, JNJ's Baby Powder had been "sold for over 100 years," "was a historical product . . . from the 1890's" and was referred to as "[JNJ's] flagship product."[62]

156. An August 4, 1999, Communication with Europe Strategic Planning states, "classic Johnson's Baby Powder fragrance is the most recognizable fragrance in the world". JNJ 000559770.

[61] *Id.* It is my understanding that other experts will discuss the specific aspects of asbestos and talc with asbestiform fibers (fibrous talc).
[62] Trial Testimony of Dr. John Hopkins in *Barden v. Brenntag North America, et. al*, MID-L-0932-17AS, July 22, 2019, at pp. 102:10-104:1.

157. A June 20, 2003, JNJ email titled "JB Powder w China Talc" references baby powder as a sacred cow: "My sense is that the Baby Powder is such a 'Scared Cow' that we will just leave it alone." JNJL4T5 000004485.

158. A JNJ document dated October 5, 1976, stated that the Market Share based volume in ounces for Johnson's Baby Powder was 53.6% and for Shower to Shower was 11.1%. The other four named products together accounted for approximately 25%. JNJ000300223

159. On JNJ affiliated website ourstory.jnj.com, the home page displays the title JOHNSON'S BABY POWDER 1894: "The company's baby product business was born in 1894 when JOHNSON'S BABY POWDER hit the market."

160. A JNJ document regarding Johnson's Baby Powder Talc Aspiration states "Baby Powder represents the cornerstone of our baby products franchise." JNJNL_61_000009898.

B. JNJ was in possession of evidence and/or had concerns regarding asbestos and the safety of its product beyond what is discussed above

161. A letter to H.L. Warner, Office of General Counsel at JNJ on April 12, 1960, from W.E. Chase at Batelle Memorial Institute, concerns a patent application for "Platy Talc Beneficiation." The purpose of the study was to determine if various reagents were "effective in selective flotation of platy talc" In the chart, Summary of Flotation Experiments with Surface Active Reagents, Float Results indicated reduction but continued presence of nonplaty talc and tremolite. (D-0182). A patent was never obtained to reduce the recognized presence of fibrous talc and tremolite.

162. In a JNJ memo dated March 30, 1973, Tom Shelley, director of JNJ's Central Research Laboratories writes to Mr. Warner's colleagues: "[W]e will want to carefully consider the Pooley patents re. asbestos in talc. It's quite possible that we may wish to keep the whole thing confidential rather than allow it to be published in patent form and thus let the whole world know." J&J 0070263; JNJAZ65 000014444.

163. Medical literature beginning in the 1960s raised concerns about the presence of fibers in cosmetic talcum products.

163.1. Cralley et al. studied 22 talcum products, finding "fiber contents ranging from 8% to 30% by count of the total particulates with an average of 19%. Although the specific fibrous materials were not identified, they were predominantly fibrous talc, as shown by X-ray diffraction, with the probably [sic] presence in minor amounts of other fibrous minerals such as tremolite, anthophyllite, chrysotile and pyrophyllite." JNJ000018189.

164. The following year, in a letter to Dr. G. Hildick-Smith, dated April 9, 1969, W.H. Ashton discusses the subject, Alternate Domestic Talc Sources:

164.1. "[We] have to firm up the position the Company should have on the presence of the mineral Tremolite in talc. Your staff will have to do this for us since the objections to that mineral have been mainly medical or clinical as opposed to chemical or physical.

164.2. "The reason we have to firm up our position is that we moved into high gear on some alternate talc sources and it is normal to find different levels of Tremolite in many U.S. talcs.

164.3. "Historically, in our Company, Tremolite has been bad because it has needle type crystals. . . Over the past year or two, the medical literature has made reference to potential hazards of talcs containing Tremolite and I have seen some articles under the umbra of environmental health agencies from here and abroad which pinpoint severe objections to that mineral in talcum powders." JNJAZ55_000001073-74.

165. Dr. C. S. Thompson with R. T. Vanderbilt, copying JNJ's Dr. Hildrick-Smith replies that he has occasionally received inquiries from various individuals, including General Johnson and several pediatricians expressing concern over the possibility of the adverse effects on the lungs of babies or mothers who might inhale any substantial amounts of our talc formulations."

165.1. The possibility of litigation was also discussed: "It might be that someone in the Law Department should be consulted with regard to the defensibility of our position in the event that such a situation could ever arise."

165.2. Dr. Thompson concluded, "It is my personal feeling that until we have at least substantial evidence, based on animal work, to the effect that the presence of Tremolite in our talc does not produce adverse effects, we should not extend its usage beyond an absolute minimum previously mentioned." factsabouttalc.com 0144.pdf; JNJL61_000001535.

166. On April 26, 1973, JNJ's D.R. Petterson wrote a memo to D.D. Johnston, Subject: Windsor Minerals and Talc. That memo discusses a number of points of "considerable concern" that were discussed between JNJ's D.R. Petterson, Bill Ashton, Roger Miller and Vernon Zeitz. According to the memo, the points that were covered at that meeting were:

166.1. "1. It is our joint conclusion that we should not rely on the 'Clean Mine' approach as a protective device for Baby Powder in the current Asbestos or Asbestos-Form controversy. We believe this mine to be very clean; however, we are also confident that fiber forming or fiber type minerals could be found. The usefulness of the 'Clean Mine' approach for asbestos only is over.

166.2. "2. It is possible that the technique of identification for asbestos or asbestos-form materials will be an optical approach. It probably will be some variation of the McCrone method. This method with appropriate concentrating techniques will permit a good laboratory to identify asbestos or tremolite in a talc sample.

166.3. "3. The current medical research is confirming that it is particle shape, not chemical substance which is harmful as such-fiber-like materials will be suspect. The argument rages as to whether an aspect ratio of 3/1, 5/1, or 10/1 will be adopted.

166.4. "4. The problem then is two fold, one for Windsor and one for Baby Powder

a. At Windsor the mine is currently under the jurisdiction of the Bureau of Mines. The inspections of the mine indicate that we are well within the limits presently accepted for non-fibrous dust. Roger Miller feels that they could live within the current TLV values for fibrous talc of 5 parts per million. We don't know the impact of a TLV of 2 fibers per cubic meter.

The May 8th meeting will primarily be an information meeting on mine and manufacturing safety. We would not expect standards to be set, however, there will be agitation probably by OSHA, NIOSH, and the Consumer Group (Selikoff), to lower the standards for the industrial exposure to the same level as asbestos…

b. As for Baby Powder, the entire thrust of communications with the FDA has concentrated on asbestos as harmful fiber-like material. Sophisticated techniques have been proposed to make sure that fiber-form materials present in the samples were identified as being asbestos. The implication is that all other fiber-forms, if present, were talc or other minerals and these were safe. This posture will no longer be satisfactory. If the FDA Food Division, which is moving more rapidly than the Cosmetic Division, publishes a standard, it will probably be to ban asbestos-form or fibrous material in talc. That could eliminate the current uses of talc in packaging materials. These talcs contain widely varying amounts of tremolite or fibrous talc. Our Baby Powder contains talc fragments classifiable as fiber. Occasionally sub-trace quantities of tremolite or actinolite are identifiable (Optical Microscope) and these might be classified as asbestos fiber.

166.5. "5. We have been pursuing several alternatives to better protect our powder franchise. These include:

"a. An improvement in the flotation technique to better select platy talc, and perhaps reduce any tremolite or talc shards. The work is still in the lab and the timetable for

commercialization is unknown. It is, however, a chemical procedure and therefore would probably not require major equipment change.

"b. A program investigating two different ways of removing a large portion of the very fine particles presently found in talc. We have demonstrated the feasibility of both approaches. The equipment and process development would take between 9 and 12 months on a crash basis. Other approaches which might be less expensive or more effective, have only been talked about. A crash engineering program could be undertaken with a good chance of success in this area. It should be cautioned, however, that no final product will ever be made which will be totally free from respirable particles. We are talking about a significant reduction in fine particle count but not 100% clean-up.

"c. Corn starch is obviously another answer. The product by its very nature does not contain fibers. Furthermore, it is assimilated by the body.

166.6. "We would recommend that items 'a' and 'c' receive top priority. The Corn Starch program, is primarily one of merchandising and the development of explosion proof facilities. We would recommend this program be spear-headed by a task force under Jim Dettre.

166.7. "The flotation program is currently being worked on at Windsor by Vernon Zeitz. We would propose a task force of Zeitz, Goodman, and Ashton and Rolle, to identify the opportunities in removing fiber-like materials from the beneficiated talc, with a recommendation to Management in 30 days.

166.8. "If we are agreed with the above, then the Battelle program should be restudied to include cells of animals on a, b, and c. We might wish these to be new cells, or to delete certain cells now in the program." JNJ000251888-90.

C. JNJ failed to report to the FDA that laboratory tests found evidence of naturally occurring mineral silicate fibers of the serpentine and amphibole series. In my opinion, that failure misled the FDA over the last half a century

167. Dr. John Hopkins, 30(b)(6) corporate representative of Johnson & Johnson, testified over four days (August 16, 2018, August 17, 2018, October 17, 2018, and November 5, 2018).

167.1. Over the course of those four days, Dr. Hopkins reviewed numerous laboratory testing results of JNJ talc. His response was recorded in a chart, with a column made to document the results as provided in the testing reports. A second column was used to record Dr. Hopkins' comments regarding those results. On Dr. Hopkins' final day of testimony, he went through each result and responded with whether the results met JNJ's definition of asbestos. Hopkins Dep. Vol. III-IV.

167.2. The samples tested varied from research samples, ore, Shower to Shower, Baby Powder, medicated powders, talc, processed talc, air samples, core, and plant run samples.

167.3. According to chart D-1-AA, developed during the deposition, Dr. Hopkins answered that there were approximately 28 times when Dr. Hopkins responded that the laboratory findings met JNJ's definition of asbestos.

167.4. One of the affirmative responses was for the laboratory results set forth in a report from Walter C. McCrone Associates, Inc. dated May 8, 1974, titled "Examination of Talc Ores and Products: Benefication Processes. "In sample 66-AC-Product, the report stated, "Only one chrysotile fiber was found in this sample; a significant reduction from the level in the ore sample. Again, no asbestiform amphibole minerals were detected." JNJ 000326106 (J&J-66).

167.5. The corresponding ore sample, 66-AC-ore, reported that "Eight chrysotile fibers were found in this sample, however, their lengths were all less than 1/3 of 1 μm. No asbestiform amphiboles were observed." JNJ 000326106 (J&J-66).

167.6. In the summary section, this report stated in regards to the 66-AC-Product chrysotile fiber finding, "At the level of one fiber in a sample it is debatable whether this represents a true chrysotile level in the sample or whether it represents contamination during taking or preparation of the sample." JNJ 000326106 (J&J-66).

167.7. When asked at his November 5, 2018, deposition whether these findings met JNJ's definition of asbestos, Dr. Hopkins stated: "Q. Right. Chrysotile satisfies the [JNJ] definition of asbestos, correct? A. If chrysotile is present, it would satisfy the definition, correct." Hopkins Dep., November 5, 2018, 1238:8-12.

167.8. Another affirmative response was for the laboratory results set forth in a report from Walter C. McCrone Associates, Inc. dated September 3, 1971. titled "Preliminary Report on Examination of Grantham Ore, Medicated Talcum Powder, and Shower to Shower Talcum Powder." (J&J 257), Hopkins Dep., 1238:8-12.

167.9. The report stated, "In the medicated powder, we found one fiber of chrysotile, and we estimate that this powder contains less than 0.001 % asbestos." J&J 252, p.2.

167.10. The report further stated in the "Shower to Shower sample we found several fibers which do not show the coring typical of' chrysotile. These may be fine fibers of talc or of Ca(PO 4)2nH20 which also occur as needles. There was one very small fiber which could have been chrysotile in a field of fine talc flakes. We were unable to obtain a diffraction pattern from the sample, but we feel strongly that it may be chrysotile. Again, the percentage of chrysotile is very low, in the range of p. 001-0. 0001%." J&J 252, p.2.

167.11. At his October 17, 2018, deposition, Dr. Hopkins testified as follows:

"Q: Is it the fourth entry. The fourth entry. My bad.

A. Yes.

Q. 'Fiber of chrysotile.' Do you see that?

A. Yes.

Q. Okay. Under the Johnson & Johnson definition that's behind you, that would be asbestos, correct, chrysotile?

A. Chrysotile fiber would be asbestos, yes." Hopkins Dep., 1072:1-13.

168. In a March 17, 2016, letter to the United States Food and Drug Administration, Johnson & Johnson's, Vice President of Regulatory Affairs North America, Jethro Ekuta, responded to the FDA's February 25, 2016 "Request for Information on Talc." Ekuta stated: "JJCI talc is also evaluated for a number of additional impurities…"

168.1. Table two in the letter lists impurity testing for JJCI body powders, which included asbestos.

168.2. On the subject of asbestos, Ekuta specifically states: "**No asbestos-form structures have ever been found during any testing**." [emphasis added] JNJ 000636145, p.12 (PLT-00131).

168.3. Rather than sharing JNJ's test results with the FDA, Ekuta cited FDA surveys to the FDA: "FDA summarized its 2009 exploratory survey of marketed cosmetic grade raw material talc and finished cosmetic products containing talc, including JJCI products (Johnson's® Baby Powder and Shower to Shower® Morning Fresh Absorbent Body Powder). FDA indicated that no asbestos fibers or structures were found in samples of cosmetic-grade raw material talc or cosmetic products containing talc including eye shadow, blush, foundation, face powder, and body powder." JNJ 000636145, p.6 (PLT-00131).

168.4. Ekuta references no other results in the letter than FDA results, which FDA already had.

168.5. In my opinion, JNJ's representation to the FDA in their March 17, 2016, letter that no asbestos-form structures have ever been found during any testing was false and misleading.

D. JNJ defended its products to health agencies by representing that its products were asbestos-free and safe

i. JNJ attempted to remove talc from NTP list of carcinogenic substances

169. In a July 12, 2001, email titled "NTP – A Strategic Proposal," from Imerys' Director of Environment and Safety, Rich Zazenski, Mr. Zazenski states that "[w]ith regard to human data on 'talc not containing asbestos' [TNCA], clearly the epidemiology studies linking cosmetic talc and ovarian cancer have been the most troublesome. While everyone admits the relative risk ratios are borderline, there are simply too many studies with these low RR's to be ignored." Zazenski states:

169.1. "[A]dmittedly we did not grasp upon the significance of this 'flaw' anytime in the past 10-15 years when these studies were being published.

169.2. "The NTP draft background document brought to life the uncertainty of the purity of the 'cosmetic' talcs used by the women in these study groups."

169.3. "If we can "invalidate" most, if not all, of the published epidemiology studies by demonstrating that sufficient doubt exists as to the purity of the cosmetic talc used prior to the mid-1970s, then it is likely that NTP might defer any reconsideration of 'talc not containing asbestos (TNCA).'

169.4. "In order to accomplish this objective, two key technical points are required. One, the published literature on the quality of cosmetic talcs prior to the 1970's must be sufficient and persuasive (in that cosmetic talc may have contained asbestos). Secondly, there must be published data that authenticates that asbestos is a risk factor for ovarian cancer. I believe we can document both of these points sufficiently to construct a well-referenced 'White Paper' for NTP . . .

169.5. "Our 'White Paper' can effectively invalidate the only 'troublesome human data that NTP has for TNCA. I am going to investigate the literature on crystalline silica and ovarian cancer to see if this can 'compound' the quality dilemma . . . That would mean that cosmetic talcs (in the past) might have contained two substances that have been declared known human carcinogens. This type of information would irrefutably invalidate the conclusion of the epidemiology studies for TNCA."

169.6. "Last thought – I recognize the potential dangers in digging up this information – but were it not for this specific quality issue, we would be preparing now for a very dim future in the talc business." IMERYS239757-8.

170. A January 2, 2002, Luzenac[63] document titled "Principal Argument for Adopting Luzenac America's NTP Strategy" states, "We engaged the council of the Center for Regulatory Effectiveness ('CRE') in November 2000 for the purpose of providing us direct assistance in developing a business strategy to challenge the NTP talc review. CRE 'knows' NTP.

170.1. "From the beginning, CRE has recommended that we adopt an aggressive (professional) approach with NTP. Our technical (and legal) arguments have alternated between Luzenac and CRE letterhead - designed to maximize the intended effect.

170.2. "CRE believes the request for by Dr. Olden (NTP Director) presents us with an opportunity to 'proactively' submit a detailed literature research paper that not only directly addresses the unresolved issues (mineralogy), but also other controversial issues that we anticipate will (or should) resurface (epidemiology, causation, consistency of results). It affords us the opportunity to initiate the agenda for discussions with NTP.

[63] Luzenac Group was a wholly owned subsidiary of Rio Tinto from 1988 until August 2011, when it was sold to Imerys. It was the sole supplier of J&J talc during that time period.

170.3. "In November 2000, Luzenac discovered the "fatal flaw" in the NTP report. With the help of CRE we exploited this issue with NTP which ended in the deferral decision by the NTP Executive Committee. The public record will reflect that Luzenac America was the only talc-interested-party who recognized this fatal flaw (and winning strategy).

170.4. "KEY POINTS . . . I am not at all concerned about angering CTFA or any of its members who might be customers. With our entire business literally at stake, we have the 'standing' to do what we feel is necessary in this battle for survival. As an aside, only [JNJ] and possibly one other company expressed interest in further funding of the consultants utilized by CTFA last December." Pltf_LUZ_00000093-4;LUZ000566-7.

171. In a presentation by Steve Jarvis, Head of Health, Safety and Environmental matters for Luzenac American, following NTP's final review, he stated, "Now realistically . . . there are some health issues with talc. For nearly 20 years, epidemiologists have been finding a weak, but persistent statistical link between the hygienic use of talc and ovarian cancer. However . . . . the studies are weakened by no one being able to offer any feasible 'causal' explanations as to how and why talc would cause ovarian cancer . . . . but not a multitude of other cancers in the human anatomy.

171.1. "But now we had only two months to prepare for the third NTP review meeting . . . a public meeting of the influential Board of Scientific Counselors Subcommittee. This occurred in December of last year and we achieved a very dramatic turnaround. The BSC subcommittee voted 7-3 ***not*** to list talc. [emphasis in original]

171.2. "Our successful defense strategy was threefold . . . Secondly . . . and this was our secret weapon, engage the services of the Washington based Center for Regulatory Effectiveness, CRE. Since its formation in 1996 by several ex-high ranking officials in the OMB, CRE has grown

into a nationally recognized . . . and relatively respected . . . regulatory watchdog organization. Federal agencies frequently come to them for assistance. CRE has also taken NTP to court.

171.3. "And thirdly, we decided to be aggressive. This was a fight we simply could not lose. As such, we retained expert legal counsel to ensure we would have a solid foundation for a legal challenge if necessary . . . it was the same firm which assisted CRE in their court battle with NTP . . . and we also became very aggressive in our communication with NTP and other federal agencies. We didn't let the windows of 'formal comment periods' become restrictive. We sent e-mails, faxes, overnight letters, and even telephones calls to key players in this battle . . . right up until hours before the final Executive Committee meeting. And we believe these strategies paid-off.

171.4. "While we certainly would have preferred a total victory - where NTP declared talc was not a human carcinogen . . . we were relieved to at least get the review process 'derailed' for now . . . at least we have some 'breathing space' to prepare a thorough, scientific defense of talc.

171.5. "One of the issues we plan to focus on is demonstrating to NTP that virtually all of the epidemiology studies they previously used must be declared invalid for use in assessing talc 'not containing asbestos.' This will be an expansion of the 'Fatal Flaw' defense Luzenac employed in the first review on talc. Additionally, we believe the latest epidemiology study which IS valid with regard to talc quality . . . it's called the Gertig study[64] . . . and which happens to be the largest

[64] Gertig, published in 2000 reported data from the Nurses' Health Study. Gertig accepted that "[c]osmetic talc may have been more likely to contain asbestos fibers prior to 1976, before voluntary guidelines were proposed", citing Harlowe, a 1992 case-control study Gertig also affirmed the migration of talc into the peritoneal cavity and ovaries, stating "Talc is able to migrate through the genital tract and gain access to the ovaries because talc fibers have been detected in benign and malignant ovarian tissue." Gertig found an increased, but not statistically significant, risk of all epithelial cancer with ever use of perineal talc (RR 1.09 (0.86-1.37)) and a statistically significant association with ever talc use and serous ovarian cancer (RR 1.40 (1.02-1.91)), the most common subtype of epithelial ovarian cancer – accounting for >50%.

study as well . . . shows no increased risk of ovarian cancer. The significance of this study must be more heavily weighted than prior studies.

171.6. "One last point……lest we get complacent……regardless of what happens with NTP, we also have to keep an eye out for IARC. IARC reviewed talc back in 1986 and concluded there was insufficient evidence of talc carcinogenicity in humans. We are hoping that this NTP activity doesn't stimulate IARC conduct an 'end-run' around NTP declare talc a possible human carcinogen . . . because I think you all know, we do not have the ability to become an active participant in that relatively 'closed' process. Pltf_IMERYS_00044439; IMERYS-A_0021921.

172. These documents show that talc manufacturers argued to the NTP that talc prior to 1970's had asbestos and that was the reason for the increased risk in epidemiologic studies. They imply that something changed in the manufacturing process that yielded asbestos free talc.

173. If it was the voluntary adoption of the CTFA testing standard in 1976 that changed, that supports the notion that the talc mines always contained asbestos, and it was the testing that improved the quality of the talc.

174. According to industry reviewers, "In 1976, specifications for cosmetic talc requiring that no detectable fibrous, asbestos mineral be present were developed. Therefore, this report will only address the safety of talc that does not contain asbestos. Because the specification was developed in 1976, that year was used in determining what data are more likely relevant to the safety of cosmetic talc; therefore, some studies performed prior to 1976 may not be relevant to talc as currently used in cosmetics, and they might not be included in this assessment." Fiume 2015.

ii. JNJ attempted to preempt IARC's designation of talc as carcinogenic and didn't update MSDS based on the IARC designation

175. IARC found in 1987 that there was sufficient evidence for talc containing asbestiform fibers to be considered carcinogenic (Group 1 known human carcinogen); the evidence was

considered insufficient for talc not containing asbestiform fibres (Group 3 not classifiable). IARC 1987.

176. In 2006, the Working Group met again to consider the evidence for talc without asbestiform fibres, considering evidence up until 2006. Although JNJ described the IARC process as "relatively closed," JNJ still attempted to influence the process.

177. In an email discussion with CPCUS (JNJ Consumer Products Division) members regarding having input into the IARC process dated August 29, 2005, the following was considered:

177.1. "It is VERY difficult to have any impact on the IARC, and this has recently become more difficult by rule changes that make industry input difficult and suspect. CTFA advised that the best we can do was to ask Dr. John Hopkins to follow a process called "Self-Nomination." And offer his name to IARC as a talc expert. I have asked John to do this and he agreed. I provided John with the proper weblink. We have some hope that [JNJ]'s reputation and our major commitment to talc might make John a valuable asset to the IARC (maybe?). CTFA also advised that Dr. Muscat is already involved with another IARC committee. Dr. Muscat and Huncharek are experts that are working with us on white papers for NTP and whom we respect. CTFA will ask Dr. Muscat and Huncharek to also self nominate for IARC. We would be happy if one of these experts was involved in the process." JNJ000003911.

178. In an email dated October 17, 2005, titled IARC Talc Review, CTFA sought support for the cost of Observers near the IARC Working Group meeting from JNJ. A "war room was to be operated near the IARC facility to serve as a meeting and communication site where Observers can go research issues." JNJ 000003915; JNJ000004015.

179. Although not a member of the Working Group, Dr. Muscat, a JNJ consultant, attended the meetings as an observer and confidentially reported back to Luzenac through the law firm Crowell & Moring. (P334 JNJ000003969). On February 8, 2006, Dr. Muscat relayed the Working Groups epidemiology discussion including his "introduction into the discussion of the fact that the talc-diagram studies (supported by JNJ) did not show a relationship; with the scientific premise that talc-coated diaphragm would be a more plausible and direct route of exposure than perineal dusting. Evidently, the Working Group was not going to consider, or even be aware, of the negative talc-diaphragm studies . . . . It is critical that the Support Team provide scientific reasoning to knock the underpinnings from the Cramer et al. studies. P334 JNJ000003969.

180. IARC listed talc without asbestiform fibers as a possible carcinogen (Group 2b). Following the designation, Imerys added the following to its Material Safety Data Sheet (MSDS) for talc:

180.1. "IARC (2006 in preparation) Has [sic] concluded that perineal use of talc based body powder is possibly carcinogenic to humans (Group 2B). This is not a route of exposure relevant for workers and applies to one specific use of talc only." IMERYS 049953.

181. In a January 19, 2005, email Dana Mickel (CPCUS) with the subject "MSDS Carcinogenic Rating," stated:

181.1. "I wanted to bring to your attention that a new field has been added to the Wercs (the system that is used to generate product MSDS) that identifies carcinogenic or suspected carcinogenic ingredients. Three of our products for the February launch have been flagged thus far with this warning. One of the products is Shower to Shower® Shimmer Effects Body Powder, Project Shimmer has been identified with 41.95% Talc. The other two are Aveeno® Lip

Relief Medicated Therapy, Project Angelina and Aveeno® Lip Relief Medicated Therapy Stick, Project Jagger both having Camphor at 1.1%. I do believe that a few other products will be flagged upon Scott's review later this week as well. The attached spreadsheet will help you identify where the carcinogenic classification of ingredients is derived from. JNJ 000390337.

181.2. The email contained two attachments:

181.2.1. "ProjectShimmer.rtf" that stated, "The below component(s) have been defined as a cancer-suspect agent by a worldwide reputable agency" and lists Talc. JNJ000390340

181.2.2. "J&JCaringenciList.xls" [sic][65] the following excerpt

CAS	Name	JNJ	ACGIH	IARC	NTP	OSHA	CA Prop 65	EU Annex I	Australia	Japan	Korea	Mexico
68952-81-8	TAIL GAS, PETROLEUM, THERMAL-CRACKED DISTILLATE, GAS OIL AND NAPHTHA ABSORBER	O						K	O			
68308-12-3	TAIL GAS, PETROLEUM, VACUUM GAS OIL HYDRODESULFURIZER, HYDROGEN SULFIDE-FREE	O						K	O			
68478-34-2	TAIL GAS, PETROLEUM, VACUUM RESIDUES THERMAL CRACKER	O						K	O			
	TALC	K	K	K			K			K		
14807-96-6	TALC (MG3H2(SIO3)4)	O										O
10540-29-1	TAMOXIFEN	K		K	K		K					
	TAMOXIFEN AND ITS SALTS	K					K					

JNJ 000390346.

In a second tab labeled "REG," TALC is listed as A1 (ACGIH) and 3 (IARC). TALC (MG3H2(SIO3)4) is listed as A4 (ACGIH) and 3 by IARC. JNJ 000390346.

181.3. In response, Robert A. Predale stated, "Do NOT send out any MSDS with this statement on it!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!! I will discuss with Joan, Steve and Paul and get back to you." JNJ 000390337.

[65] The email gives the legend as follows:
"K- 'The below component(s) have been defined as a human carcinogen by a worldwide reputable agency.'
0 - 'The below component(s) have been defined as a cancer-suspect agent by a worldwide reputable agency.'
Under review- 'The below component(s) are under review for carcinogenic effects by a worldwide reputable agency.'"

181.4. On February 2, 2005, Joan Casalvieri responded, "Talc is listed as both ACGIH A4 and IARC class 3 - again not classified as a human carcinogen. There is another listing for talc that is class 1 'confirmed human carcinogen' but we suspect this must be the grade that is known to contain asbestos. Please clarify if you know what this listing is. Cosmetic talc that we use in our products does not contain asbestos and is not carcinogenic. We are aware that the NTP is looking at talc as part of the 12th ROC. We are very involved in that exercise and will be on top of the findings." JNJ 000390347.

181.5. She further states, "I would suggest that the Wercs system needs to be modified so that materials that are not classified are not identified as requiring a warning statement. As toxicologists we need to be able to make assessment calls on our finished products based on the intended use. We do a very thorough internal safety assessment on our products and are assured that they are safe in general and specifically do not contain cancer causing ingredients. The scientific data and our safety assessment do not warrant that a warning statement be placed on our products." JNJ 000390347.

182. In 2006, IARC upped its classification of talc not containing asbestiform fibers to 2B, "Possibly carcinogenic to humans." IARC 2007.

183. Even after the 2006 classification, JNJ did not add a warning to its MSDS for talcum powder products.

184. In a letter dated July 12, 2006, Eric Turner, VP of Health and Sustainability with Luzenac/Imerys wrote to Mark Ellis, President of Industrial Minerals Association of North America regarding Luzenac's decision to forego any further funding of the University of Vermont talc study (re: "Mossman" study). Turner explained, "When IARC concluded their review and classified 'perineal use of talc-based powders' as a Group 2b carcinogen, we began to

question the value of proceeding any further with the Mossman study. To put it in the vernacular, the 'horse has already left the barn.' Due to the considerable costs involved and deadlines no longer a factor, Luzenac (Rio Tinto Minerals) made the business decision that the potential value of this study was greatly diminished and did not warrant any further pursuit at this time." LUZ001443.

184.1. A deleted sentence stated, "one of their primary arguments is that there are simply too many positive epidemiology studies published to stem the tide of negative sentiment." LUZ001443.

iii. JNJ attempted to prevent actions by Health Canada to remove talcum powder products from the market

185. Following the release of a draft Health Canada report, "Screening Assessment Talc ($Mg_3H_2(SiO_3)_4$),[66]" JNJ submitted a briefing document that was critical of Health Canada's process and conclusions and defending the absence of asbestos in talc even though Health Canada made their conclusions based on a non-asbestos containing talcum powder. Johnson's Baby Powder: A Comprehensive Review is dated March 17, 2020. JNJTALC001465273.

185.1. In April 2021, Health Canada published its Final Assessment[67] regarding the health risks of the genital use of talcum powder, in particular, ovarian cancer. Based on the information provided in the CIR review article (see discussion), Health Canada stated: "Historically, some talc source materials were contaminated with asbestos. However, in 1976, the Cosmetic Toiletry and Fragrance Association (CTFA) set purity standards for cosmetic-grade talc resulting in a reduction in asbestos levels in cosmetic products. (Fiume et al. 2015).

[66] https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/draft-screening-assessment-talc-mg3h2sio34.html

[67] Screening Assessment Talc ($Mg_3H_2(SiO_3)_4$), Chemical Abstracts Service Registry Number 14807-96-6, environment and Climate Change, Health Canada, April 2021.

185.2. "Cosmetic-grade talc should comply with USP standards that require a limit of 20ppm lead and an absence of asbestos (Fiume et al. 2015) . . . "The cosmetic-grade talc used in the health effect studies in this assessment were considered to be free of asbestos." Nonetheless, Health Canada found: "With regards to perineal exposure, analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer. The available data are indicative of a causal effect." The human health effects portion of the Assessment underwent external peer review.

186. JNJ made the argument in front of Health Canada that talc and asbestos were different.

186.1. JNJ's table compares the characteristics of asbestos and talc

Table 1. Comparison of Characteristics of Asbestos and Talc

	Asbestos Minerals	Talc
Silicate mineral group	Amphibole[a] Serpentine[a]	Clay minerals
Mineral name/idealized chemical structure	• Tremolite $Ca_2Mg_5Si_8O_{22}(OH)_2$ • Actinolite $Ca_2(Fe^{2+}Mg)_5Si_8O_{22}(OH)_2$ • Anthophyllite $Mg_7Si_8O_{22}(OH)_2$ • Amosite $Fe^{2+}{}_7Si_8O_{22}(OH)_2$ • Crocidolite $Na_2(Fe^{2+}{}_3Fe^{3+}{}_2)Si_8O_{22}(OH)_2$ • Chrysotile $Mg_3(Si_2O_5)(OH)_4$	Talc $Mg_3Si_4O_{10}(OH)_2$
Crystal habit	Asbestiform (amosite and crocidolite) Asbestiform or non-asbestiform (chrysotile, tremolite, actinolite and anthophyllite)	Non-asbestiform (platy)
Particle characteristics	Asbestiform fibers • High aspect ratio (length-to-width) • Diameter: <0.25-0.5 µm [18,19] • Majority respirable [19] • Flexible	Sheet fragments • Low aspect ratio • Particle size: 4-15 µm; <37-74 µm[b] • Minor fractions considered respirable [21]

a: Tremolite, actinolite, anthophyllite, amosite, and crocidolite are amphibole minerals, and chrysotile is a serpentine mineral [17]
b: Based on 200 to 400 mesh used to size cosmetic talc [21]

186.2. JNJ also stated, "[i] n order to distinguish between asbestos and other minerals and confirm the absence of asbestos in Johnson's Baby Powder, [JNJ] uses highly advanced, reliable, and reproducible techniques, including x-ray diffraction, polarized light microscopy, and transmission electron microscopy. JNJTALC001465273, p. 14.

186.3. "[JNJ] uses talc that meets or exceeds standards for both cosmetic and pharmaceutical grade talc. [JNJ] has rigorous testing standards and has never confirmed the presence of asbestos in Johnsons Baby Powder or any other [JNJ] product containing talc." JNJTALC001465273, p. 14.

186.4. JNJ argued in front of Health Canada "Regarding Potential Ovarian Findings:"

- "Proposed conclusions represent a complete reversal from previous scientific engagement;
- "Perhaps influenced by civil litigation outcomes in the US (not science based);
- "More appropriate and comprehensive application of Bradford Hill considerations required;
- "Explore all likely explanations for epidemiological findings (balanced by considerations for mode of action and biological plausibility);
- "Appropriate weighting of unpublished, non-peer reviewed studies (critical studies selection) is necessary" P-1206.

186.5. JNJ further argued "Additional General Considerations": "Proposed conclusions regarding ovarian toxicity do not consider the full body of scientific evidence and are at odds with other bodies of largely the same scientific evidence (US FDA, NCI, CR, etc.). P-1206.

187. In the late 70's, Vernon Zeitz, the Director of Research at JNJ's Windsor Minerals, in a handwritten letter to his colleagues, including Dr. Hildick-Smith, wrote in frustration after the

then Department of Health Education and Welfare contacted him about a government study of Vermont talc workers: "I am also aware that this approach is not the way that [JNJ] does things, however, most wars are not won at peace talks around the conference table, but are won on the battle field by legions who are the most ruthless who have the greatest desire to win, along with possessing the best overall strategy and weapons. If we are to be those legions, it is imperative we overcome the inertia of our past to modernize and mobilize our defenses and offenses so we enter into battle with the outcome assured." WTALC00007366, PX9718, J&J-87.

188. In my opinion, JNJ decided in the 1970's to aggressively defend its product. That strategy kept their product on the market for fifty years but put the public's health at risk. It need not have been that way if JNJ was willing to bear any additional cost and reformulate the product.

189. In my opinion, a reasonable and prudent company, would have reformulated the product in the 1970's.

E. JNJ through CTFA created the impression beginning in 1976 that changes in testing resolved the asbestos controversy in talc; yet JNJ claimed its testing never found asbestiform particles

190. In a 1977 Status Report – Defense of Talc Safety, written by J&J's George Lee, Mr. Lee states:

190.1. "The past two months have seen no disruptive influences and to the contrary, the cosmetic talcs have enjoyed confirming reassurance from several independent authoritative sources that they are assessed to be free of hazard for normal consumer use.

190.2. "We attribute this growing opinion to the fact that (1) the existence of CTFA's self-regulating cosmetic grade talc specification has become common knowledge and that (2) favorable data from the various [JNJ] sponsored studies have been disseminated effectively to

the scientific and medical communities in the U.K. and U.S." J&J-0146266-69; JNJMX68_000013482-85.

191. In my opinion, the problems with the CTFA testing methodology J4-1 were: 1) it did not address chrysotile; 2) it had some very significant detection limits because it did not include transmission electron microscopy; 3) it was not apparently accompanied by any changes in mining or manufacturing which made the product safer; 4) and it failed to report fibrous talc. Moreover, the repeated assertion by JNJ that there have never been any positive tests for asbestiform particles suggests that the CTFA testing methodology J4-1 did not accomplish anything. To be useful CTFA's testing methodology would have to detect some positive samples for asbestiform particles.

192. JNJ continued to tell the public that its testing methodologies made the product asbestos-free and that no asbestos-form structures have ever been found during any testing. JNJ 000636145, p. 12 (PLT-00131).

192.1. A 2013 draft for the Home Page of JNJ's SafetyandCareCommitment.com website included a heading with these remarks and edits:

1. "Talc has over 100 years of ~~safe~~ use in personal care products.
2. JOHNSON'S talc products are made using Pharmacopeial (USP) grade talc to ensure it meets the highest-quality, purity and compliance standards. Our talc-based consumer products are ~~have always been~~ (we cannot say "always") asbestos free, as confirmed by regular testing conducted since the 1970s.
3. We also make JOHNSON'S Baby Powder that contains cornstarch.

JNJTALC000067661(P-83).

193. Numerous epidemiologic studies accepted the concept that talcum powder became asbestos free beginning in 1976, for example:

193.1. Gertig (2000): "Cosmetic talc may have been more likely to contain asbestos fibers prior to 1976, before voluntary guidelines were proposed."

193.2. Huncharek (2003): "Voluntary guidelines were established by the cosmetic industry in 1976 to limit the content of asbestiform fibers in commercial talc preparations, although the magnitude of the risk of ovarian cancer as a result of perineal exposure to talc remains unclear."

193.3. Berge (2017): "Furthermore, talcum powders for domestic use in the USA have been virtually asbestos free since the 1970s (Rohl et al., 1976)."

193.4. Schildkraut (2016): "Although particles of asbestos have been found in older body powder formulations, particularly prior to 1976, more recent body powder formulations no longer contain asbestos."

193.5. Cramer (1982): "Generic 'talc' is seldom pure and may be contaminated with asbestos, particularly in powders formulated prior to 1976."

194. Health agencies also accepted the concept that talcum powder became asbestos-free beginning in 1976:

194.1. Health Canada stated, "Historically, some talc source materials were contaminated with asbestos. However, in 1976, the Cosmetic Toiletry and Fragrance Association (CTFA) set purity standards for cosmetic-grade talc resulting in a reduction of asbestos levels in cosmetic products."[68]

[68] Screening Assessment Talc ($Mg_3H_2(SiO_3)_4$), Chemical Abstracts Service Registry Number 14807-96-6, environment and Climate Change, Health Canada, April 2021.

194.2. The American Cancer Society Website "Talcum Powder and Cancer" states, "[i]n 1976, the Cosmetic, Toiletry, and Fragrances Association (CTFA), the trade association representing the cosmetic and personal care products industry, issued voluntary guidelines stating that all talc used in cosmetic products in the United States should be free from detectable amounts of asbestos according to their standards."[69]

195. In my opinion, the acceptance of JNJ's concept that changes in testing resolved the asbestos controversy in talc by researchers and health agencies impeded the resolution of important safety issues.

F. JNJ defended its product by representing that there could be safe levels of asbestos when there was no known threshold

196. On September 6, 1974, Dr. Nashed of JNJ wrote to Dr. Schaffner at FDA, stating that "[JNJ] has been cooperating with the Cosmetic, Toiletry and Fragrance Association Subcommittee on Asbestos in Talc," copying multiple individuals. JNJNL61_000013575.

196.1. He further states that: "In an effort to answer the question about the required degree of sensitivity of the method of assay for asbestos in talc, our statistical group has made an estimation of a theoretical safe level of asbestos fiber in baby powder utilizing the TLV for asbestos and the data on dusting of baby powder." JNJNL61_000013575.

196.2. He concluded: "Therefore, methods capable of determining less that 1% asbestos in talc are not necessary to assure the safety of cosmetic talc." Plaintiff's Exhibit 2489, JNJNL61_000013575.

197. In a memo with letter dated February 13, 1975, on letterhead "Johnson & Johnson Baby Products Company" reporting on a meeting with CTFA and FDA, CTFA's Dr. Estrin "indicated

[69] https://www.cancer.org/cancer/risk-prevention/chemicals/talcum-powder-and-cancer.html

that the purpose of our meeting was to present the analytical methodology which had been developed by the CTFA Task Force as applicable to cosmetic talcs. Representing the FDA were Dr. Schaffner, Mr. Eiermann, Dr. Yates, and others. Representing CTFA were Dr. Estrin, Mr. Sandland, Mr. Lee, and others. Discussions at the meeting included:

197.1. "When questioned as to FDA efforts and progress in the approach of 'concentrating asbestos' to increase the level of sensitivity, Dr. Yates replied in a tone of frustration that all attempts have met with failure; they had investigated heavy density liquid separation.

197.2. "Dr. Yates did not state that efforts would be continued in this direction.

197.3. "Dr. Schaffner agreed that no one has purported to have seen chrysotile in cosmetic talc except Professor Lewin.

197.4. "Dr. Berdick made the point that if chrysotile is not expected to be found in talc, then the FDA should not propose regulations to cover chrysotile.

197.5. "Mr. G. Sandland stated that a regulation of 1% asbestos in talc was not only achievable by thoroughly tested methods., but also gave a safety factor of 48,000 (Silvertson calculation). Mr. Eiermann bluntly said that the calculation was wrong since the standard of 2 fibers/cc is not a time weighted average.

197.6. "Before we had a chance for rebuttal Dr. Schaffner said that the Silvertson calculation was foolish since no mother was going to powder her baby with 1% of a known carcinogen irregardless of the large safety factor.

197.7. "Dr. Schaffner emphasized that there is an ultimate and more important need for talc clinical safety data in order to satisfy the consumerist advocates. The writer assured him that this would be forthcoming from [JNJ]. Plaintiff's Exhibit 60; J&J-0089804.

198. In trial testimony, John Hopkins confirmed that there is no safe level of asbestos.

Q: Now on the issue of the safe level [of asbestos] is zero, J&J agrees with that?

A: Yes.

199. In a January 16 memo regarding a meeting with FDA Commissioner Schmidt, JNJ's Dr. Nashed stated: "Our very preliminary calculation suggests that substantial asbestos can be allowed safely in a baby powder. J&J-0132008, Plaintiff's Exhibit 2456.

200. In my opinion, JNJ defended its product by representing that there could be safe levels of asbestos when there was no known threshold in the 1970's and put the public at risk because there is no known safe level of asbestos.

G. JNJ opposed testing methods that would improve the sensitivity of their testing and reduce the number of false negatives

201. As noted above, JNJ was aware that false negative results would occur with its testing methodology, in part because these tests were not sensitive enough. In light of the fact that asbestos was a known carcinogen with no known threshold, in my opinion, a reasonable and prudent company would attempt to improve the sensitivity of its testing so as not to put the public at risk.

202. With regard to its approach to the improving of its laboratory methods, JNJ took the following actions:

202.1. In 1973, JNJ's Dr. Nashed, replying to Mullen's questions regarding 9-28-72 regulations proposed by FDA, stated, "The proposal will have no impact on our talc since the method of analysis in the proposal will show that our talc is acceptable. However, if they change the method, we may have problems." JNJAZ55_000006212.

202.2. In a May 16, 1973, letter, JNJ's Dr. Shelley wrote to colleagues that he was planning to meet with scientists in England regarding "specs for analyzing talc for asbestos." The

scientists there were considering a "method of concentrating the asbestos so as to be able to analyze by X-ray." JNJAZ55_000001893.

202.3. In his letter, Dr. Shelley described the "Pooley Method" which uses "two techniques for preconcentration of chrysotile and tremolite in talc by x-ray diffraction analysis . . ." Dr. Shelley further stated, "The limitation of this method is that it may be too sensitive." JNJAZ55_000001896.

202.4. A J&J memo dated November 24, 1976, to Mr. George Lee from W.H. Ashton discussed "a disturbing proposal request which the FDA has currently made available to qualified bidders." The subject was the Separation of Asbestos in Foods, Drugs and Talc for Identification and Determination. Mr. Ashton expressed his concerns:

202.4.1. "I find this proposal more disturbing than other proposals up to now because it aims at separation and isolation of asbestos from a wide scope of products and animal tissues. Up to now, our main problems have had to do with identification, whereas, now it looks like the FDA is getting into separation and isolation methodology which will mean concentration procedures.

202.4.2. "As I have pointed out many times, there are many talcs on all markets which will be hard pressed in supporting purity claims, when ultra sophisticated assay separation and isolation techniques are applied. Pltf_JNJ_00031883.

202.5. A report from the Colorado School of Mines, prepared for JNJ titled "A Procedure to Examine Talc for the Presence of Chrysotile and Tremolite-Actinolite Fibers" stated:

202.5.1. "The purpose of this document is to report the methods used at the Colorado School of Mines Research Institute for detection of chrysotile and/or tremolite-actinolite in samples predominantly composed of talc.

202.5.2. "As the impurity level becomes very low (<<1%), it is necessary to examine increasingly larger amounts of sample in order to detect the impurity. As a result of the requirement to detect the proverbial "needle in a haystack," we have evolved a procedure which preconcentrates the impurities prior to examination.

202.5.3. "A procedure to detect the presence of chrysotile and/or tremolite fibers in talc is presented. The procedure involves two heavy liquid separations to concentrate any chrysotile and tremolite-actinolite which may be present.

202.5.4. "The heavy liquid concentrates are examined by optical microscopy for the presence of optical size (greater than approximately 2 microns in length) fibers of chrysotile and/or tremolite-actinolite. The procedure is capable of detecting fibers present at a level of approximately 10 ppm or less. JNJ 000268039.

202.6. In a February 1975 letter from Sloane to Dr. R. Rohl, Mr. Sloane, in commenting on a concentration technique, stated: "We deliberately have not included a concentration technique because we felt that it would not be in worldwide company interest to do this." PX58, JNJ000063925, JNJ0069873.

203. When there is no known safe level of a carcinogenic substance, having the ability to detect the smallest feasible quantities is paramount.

204. In my opinion, when dealing with known human carcinogens, safety cannot be substantiated in the absence of being able to detect the smallest feasible quantities of those carcinogens.

205. In my opinion, in the absence of being able to detect the smallest quantities, there can be no representation that the baby powder is free of carcinogenic substances.

206. Yet, JNJ made repeat representations that their baby powder was asbestos free.

207. Making claims that the product was asbestos free fails to tell the whole story unless the limit of detection is explained.

208. Non-detection is not equivalent to asbestos-free and can be easily misinterpreted.

209. Making claims to the public that Baby Powder contains no asbestos is misleading unless its testing methods detect the smallest quantities of asbestos.

210. In my opinion, making claims that its product was asbestos free without vigorous efforts to improve the sensitivity of the testing methods is concerning.

211. In my opinion, making such claims while opposing efforts to improve the sensitivity of the testing methods is evidence that JNJ defended its powder while putting the public at risk.

212. In my opinion, for more than fifty years JNJ made representations that were misleading and not transparent.

213. The sampling, detection, and interpretation of asbestos in talc is complex. A sophisticated company like JNJ deals with those questions all the time.

214. In my opinion, confronted by the laboratory, geological and epidemiological evidence in its possession, a reasonable and prudent company would reformulate the product or stop selling it.

H. JNJ had evidence that existing methods could lead to false negative results or other irregularities that could result in negative test records

215. A September 13, 2011, presentation, titled "Fiber Management Overview," discusses "Potential False Negatives." The slide identifies, "[e]xisiting methods [that] may lead to false negative results[70] if:

[70] Imerys also noted the potential for false positive results: "Existing methods may lead to false positive results if: Chlorite is present (interference with serpentine by XRD). Zinc stearate is present in cosmetic (interference with amphibole by XRD. XRD is used without microscopy follow-up. Identification by morphology alone without PLM/Dispersion staining. Other elongated inorganic phases are present. Platy particles viewed on edge. Presence of organic fibers (i.e., bag house fibers)." PLT-04451, p. 14.

215.1. "Asbestos is present, but is below XRD detection limit.

215.2. "Chrysotile is present, but is below resolution limit of PLM.

215.3. "Product is ground too finely for adequate PLM characterization (not typical for personal care products).

215.4. "TEM underestimates due to exclusion of larger particles."

215.5. Imerys continues by discussing, "[false] negative results on questionable ore can result in:

215.6. "Potential worker health problem. [emphasis added]

215.7. "Potential public health issue."

215.8. "Significant litigation potential."

215.9. Imerys also stated on a previous slide, "False negative results on questionable ore can result in:

215.9.1. "Potential litigation risk.

215.9.2. "Potential unnecessary waste of ore."

PLT-04451, p.14-15.

216. In my opinion, in light of the fact that JNJ had evidence that (a) its existing methodologies could produce false negatives that would fail to identify asbestos particles when they were present, and (b) the asbestos was a carcinogen for which there was no known safe exposure, JNJ had a responsibility to take all feasible steps to develop either a methodology that reduced the amount of false negatives as low as reasonably possible or to stop selling the talc product.

217. It also appears that human factors may have contributed, deliberately or not, to the reporting of negative test results.

217.1. In an email from Luzenac's Julie Pier to Bruno Ducasse, with the subject "RE: Clivage [sic] fragments," Pier writes, "R.J. Lee has a different approach to the whole thing. They believe that if you can find a hint of a diffraction pattern from another mineral while you are looking at the amphibole fiber, then you can call the fiber 'transitional' and not truly amphibole. The analyst told me that when she finds a tremolite fiber, she will tilt the stage until she can see a talc diffraction pattern come into view. I am very skeptical of this. There is a lot of scatter of the electrons and you can sometimes get interference in the diffraction patterns from adjacent particles, especially at a higher title. I have spoken to someone at the USGS about this, and they are also skeptical about the R.J. Lee philosophy."[71] IMERYS446794.

217.2. A May 17, 2001, Confidential Draft of an Interoffice Memo from R. J. Zazenski to D. D. Harris with the subject "LNAO Product Certification Program," under a heading "TEM Analysis Protocol," Zazenski states, "If asbestos fibers are present above the detection limit in samples from **current mining and production**, a second sample will be prepared and re-analyzed. If the second analysis fails to confirm the first, the results from the sample will be formally recorded as '**asbestos detected, not confirmed.'** If the second analysis confirms the first, the sample will be sent to RJ Lee Group for independent validation. The results of the RJ Lee analysis

[71] *See* also May 16, 2016, letter from George Lincoln at R.J. Lee to Sid Shankar at JNJ responding to an audit. The letter states, "In several instances, a CAR or investigation was not opened to document why there was presence of chrysotile (white asbestos) in J&J analytical reports." It also stated, "It indicated that Sample in ID# 3138494 had multiple chrysotile particles. Re-preparation could not duplicate the original results . . . As a result, the samples were re-analyzed . . ." If further states, "The re-test samples were re-analyzed using specific talc parameters on the XRF which should have been applied when the original samples were analyzed. They were not applied because the analyst who typically runs the XRF was out of the office and her backup did not apply the talc specific settings . . . Corrective Action, CAR-16012-XRD, has been opened in order to document the need for analyst retraining according to SOP XRD.019 and XRD.026 in order to provide a standard procedure" JNJ000521616. On June 28, 2016, letter from George Lincoln at R.J. Lee to Michael Lesh at JNJ, stated, "RJ Lee Group staff acknowledge that communication in a formal narrative to the client in terms of re-testing irregular results prior to the issuance of a final report was lacking." JNJTALC001042772. *See* also PLT-019, IMERYS 308446.

will be recorded as the formal, final result for that sample." (emphasis in original) IMERYS 039204.

218. In my opinion, there is evidence that the opportunity for bias was introduced into the asbestos testing programs.

219. It appears that it was not uncommon practice for J&J's testing program to re-test samples when a positive test was reported. Re-testing would be appropriate if a pre-testing protocol governed such conduct and there were methods to assure that bias would not be introduced into the testing process. Re-testing outside of an agreed upon protocol can lead to what is known as "testing into compliance." FDA has said in other contexts, "'testing into compliance' is unscientific and objectionable."[72]

220. Certainly, a sophisticated company such as JNJ recognizes the potential for introduction of bias in re-testing.

221. As late as 2016, JNJ's selected third party testing laboratories were arguing against using a "conservative" approach in talc testing. R.J. Lee's Drew R. Van Order wrote to Dr. Stephen Raven of Johnson and Johnson on March 10, 2016, and stated,

221.1. "Specification of a conservative aspect ratio (3:1) instead of a value of 20:1 to 100:1 as is found in global analytical procedures will lead to increased variability in the reported asbestos content in the absence of the consideration of morphological criteria (e.g., very thin fibrils (generally thinner than 0.5 um) occurring in bundles or masses and often showing curvature). The variability results from the inclusion of non-asbestos minerals that are elongated simply due to fracture mechanics, not due to the growth of a fiber. These minerals may include the talc itself." JNJTALC000276224-5.

[72] "Guidance for Industry Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production," U.S. Department of Health and Human Services, October 2006, p.8.

222. In my opinion, a reasonable and prudent manufacturer, when confronted with a carcinogen for which there is no known human threshold, would adopt procedures that were most protective (i.e., "conservative") of the public health, even at the risk of increased variability.

222.1. In contrast to the personal care product industry, the methods written for building materials have the included implication that a finding that amphiboles are asbestos. ("Existing methods written for building materials have the implication that amphibole/serpentine is asbestos." IMERYS 193653.

223. In my opinion, while microscopists and geologists have much to add to our scientific understanding, the failure of JNJ to adopt a public health approach to asbestos in talc testing, even if that led to over-inclusion and false positives, put consumers at risk.

I. JNJ failed to recognize and mitigate the potential risks of fibrous talc

224. Cralley et al. studied 22 talcum products, finding "fiber contents ranging from 8% to 30% by count of the total particulates with an average of 19%. Although the specific fibrous materials were not identified, they were predominantly fibrous talc, as shown by X-ray diffraction, with the probably [sic] presence in minor amounts of other fibrous minerals such as tremolite, anthophyllite, chrysotile and pyrophyllite." JNJ000018189.

225. In the 1973 memo from D.R. Petterson to D.D. Johnston previously discussed relating to Windsor Mineral and talc, asbestos fibers and talc fibers were distinguished. The memo stated:

225.1. "As for Baby Powder, the entire thrust of our communications with the FDA has concentrated on asbestos as harmful fiber like material. Sophisticated techniques have been proposed to make sure that fiber-form materials present in samples were identified as being asbestos. The implication is that all other fiber-forms, if present, were talc or other minerals and these were safe.

225.2. "This posture will no longer be satisfactory. If the FDA Food Division, which is moving more rapidly than the Cosmetic Division, publishes a standard, it will probably be to ban asbestos-form fibrous materials in talc.

225.3. "Our Baby Powder contains talc fragments classifiable as fiber. Occasionally sub-trace quantities of tremolite or actinolite are identifiable (optical Microscope) and these might be classifiable as asbestos fiber." JNJ00000294872.

226. In an October 11, 1972, letter from Johnson & Johnson to the FDA, W. Nashed writes, "In summary, as stated above, talc itself may contain "asbestos-form" particles that are not asbestos. There are no specific data of other information showing that talc is carcinogenic." JNJAZ55_00001362.

227. As discussed above, FDA and other government scientists have recognized that the health risks associated with particles like asbestos extend to elongated mineral particles.

228. Furthermore, IARC has categorized talc in fibrous form as a Group 1 carcinogen in the same category as asbestos.

229. In my opinion, JNJ's failure to recognize and mitigate the potential risks of fibrous talc put the public at risk.

J. JNJ implemented laboratory testing methods that had criteria that risked missing positive results of asbestos.

230. JNJ adopted a standard test method for "Analysis of Powdered Talc for Asbestiform Minerals by Transmission Electron Microscopy" dated March 8, 1989, that set a limit of quantifiable detection. Under the heading "Limit of Quantifiable Detection," J&J's test method stated:

230.1. "The detection of five or more asbestiform minerals of one variety in an analysis constitutes a quantifiable level of detection." J&J-0007920.

230.2. Dr. James R. Millette from Millette Technical Consulting discussed this setting of a quantifiable level of detection in the article, stating,

230.3. "For lack of better statistical information at the time in 1990, the publication stated a rule of thumb that the detection of five or more asbestiform minerals of one variety in an analysis constituted a quantifiable level of detection. Subsequent method of development in the area of TEM analysis for asbestos has shown that the detection of less than five fibers in a sample can provide a statistically valid result." Millette, James R., (2015). Procedure for the Analysis of Talc for Asbestos. *The Microscope*, Vol. 63(1), 11-20, 12.

230.4. Generally, a detection limit means the minimum concentration of an analyte, substance or particles, that can be measured and reported with a certain degree of confidence that the analyte, substance or particles is distinguishable from the method blank results. *See generally, for example*, 40 CFR § 136.2.

230.5. The estimated LOD, according to CDC method 7402, dated May 15 1989, is "1 confirmed asbestos fiber above 95% of expected mean blank value." Asbestos by TEM, Method 7402, NIOSH Manual of Analytical Methods (NMAM), Fourth Edition, 8/15/1994, p.1.

230.6. According to a 2019 publication of ASTM International by Bertram Price titled The Foundation for ASTM D6620 *Standard Practice for Asbestos Detection Limit Based on Counts* and Its Application as a Study Design Parameter stated:

230.6.1. "A detection limit (DL) is often, but erroneously, thought of as a quantitative boundary between measurements that are reliably differentiated from background and measurements nor differentiable from background.

230.6.2. "That is not, however, a DL's function; A DL is the mean value of a statistical distribution of measurements that have a high probability of not being confused with *below detection* measurements."[73]

230.7. In my opinion, in dealing with a known carcinogen, the test methods that are employed should use a level of detection that does not miss finding asbestos fibers that are present in the sample, taking into account the mean background level. The test methods should be sensitive enough to protect the public health.

K. JNJ's approach to the asbestos issue in talc was to initiate studies only as required by confrontation

231. In a "Strictly Confidential" memo, dated March 3, 1975, with Subject: "Management Authorization for Additional Talc Safety Studies," Dr. Petterson writes:

231.1. "Our current posture with respect to sponsorship of talc safety studies has been to initiate studies only as dictated by confrontation. This philosophy, so far, has allowed us to neutralize or hold in check data already generated by investigators who question the safety of talc.

231.2. "The principal advantage for this operating philosophy lies in the fact that we minimize the risk of possible self-generation of scientific data which may be politically or scientifically embarrassing.

231.3. "An alternative philosophy . . . would favor a more anticipatory approach. We would carry out other reasonable safety studies to continue our contradiction of generated negative data and to anticipate questions on safety which will probably be raised." Plaintiff's Exhibit 2514, JNJNL61_000016437.

[73] See generally ASTM D6620.

232. In my opinion JNJ, by adopting the approach to the asbestos issue in talc, which was to initiate studies only as required by confrontation, failed to substantiate the safety of its product.

L. JNJ created confusion and doubt when the safety of their product was brought into question

233. Per a November 13, 2000, email between Luzenac's Rich Zazenski and Erin Turner, Luzenac referenced a "Critique" by Dr. Wehner by stating, "I expessed [sic] concern about the strident, some might say arrogant, tone of his original essay. That document failed to convince (although we do not know if the style contributed to that) so this time I strongly recommend we turn it round into a collaborative style that puts the consultants who prepared the draft in the firing line, not the NTP and its venerable Counsellors. The aim should be to create a reasonable doubt in their minds that they may not be acting on the best of advice from their consultants. It is not to curse them for fools in the hope they wiii [sic] agree they are fools and change their minds. All the points stay the same just the target of the -- critisism [sic] changes." IMERYS 239407.

234. On January 4, 2001, Luzenac's Rich Zazenski sends an email to colleague Eric Turner reporting on a recent CRE meeting. Strategies for approaching and influencing health agencies were discussed:

234.1. CRE's Jim Tozzi "recommended that over the coming months, we target specific individuals at each of the agencies on the Executive Committee who might be likely be the attendees for the talc review. Then we select an issue which we want that particular individual to become familiar with before the committee meeting. For example, we target individuals within the FDA and the CPSC to focus on the weaknesses of the epidemiologic studies. Then perhaps we target individuals at OSHA and NIOSH for pointing out the irrelevance of the NTP animal study, etc.

234.2. "We dodged a bullet in December based entirely over the definition issue. However, I believe that given the issue at hand, the Draft report can be amended to remove the 'fatal flaw assumptions' by accounting for the ambiguities surrounding the content of body powders prior to 1976 in a different context.

234.3. "Essentially, if the report were to be rewritten to state that the possibility of asbestos contamination of cosmetic talc prior to 1976 should simply be accounted for as an additional 'confounding' factor in the epidemiology studies, a revote for 'talc not containing fibers' would likely go the other way.

234.4. The additional confounding factor might simply reduce the relevance of the human studies from 'sufficient' to 'limited.' Limited human studies most certainly result in a NTP listing recommendation – regardless of the relevance of the animal study."

234.5. Attendee Robert Bernstein responds: "Time to come up with more confusion." IMERYS 303828.

235. In my opinion, JNJ's defensive strategy of creating doubt and confusion failed to resolve the safety issues associated with its product.

M. JNJ Misled doctors

236. JNJ had multiple communications with the medical community. Regarding the perineal use of talcum powder and ovarian cancer, one of the most important groups were gynecologic oncologists who care for women with ovarian cancer. PLT-09808.

236.1. For example, in an email exchange in February 2016, the JNJ marketing lead for the SGO (Society of Gynecologic Oncology) asked for talking points for the annual SGO meeting. The individual was provided with the "talc facts, verbatim, that are posted on www.jnj.com." JNJTALC000250188.

236.2. This information on the document included:

1) "JOHNSON'S talc products do not contain asbestos. . .The talc used in all our global production is carefully selected and processed to be asbestos-free, which is confirmed by regular testing since the 1970s.
2) "The safety of talc is based on a long history of safe use and more than 30 years of research by independent researchers, scientific review boards and global authorities.
3) "The grade of talc used in cosmetics is of high purity, comparable to that used for pharmaceutical applications and is free from asbestos and asbestiform fibers. Cosmetic grade talc is only mined from select deposits from certified locations, and milled to relatively large non-respirable particle size (>5μm).
4) "Our sources for talc undergo comprehensive qualification. The incoming talc is routinely evaluated using a sophisticated battery of tests designed to ensure quality, safety, and compliance with all global standards." JNJTALC000250189-90."

237. In my opinion, in light of the totality of evidence in JNJ's possession regarding scientific evidence of the association of talcum powder and ovarian cancer, laboratory testing suggesting the presence of particles for which the safety was not established, and the complexities of the geologic formation of talc and asbestos, JNJ's statements to the gynecologic oncologists and the medical community more broadly was misleading because they failed to tell the whole story.

N. JNJ Described Scientists as "Antagonistic Personalities"

238. By December 1972, JNJ had already identified "Antagonistic Personalities In The Talc Story in the U.S. A. A memo from Dr. Gavin Hildrick-Smith to colleagues, including Drs. Fuller, Nashed, and Petterson, made these statements:

238.1. "The increase in the profile of talc as a potential health hazard has been actively promoted for a variety of reasons.

238.2. "The start of the attack on talc originated in England at the Tenovus Research Institute in Cardiff where a technician in microscopy published a paper.

238.3. "In the U.S.A. the leading group who initiated the attack is located in New York City and included these scientists: Dr. Sellikoff, Dr. Langer ('a microscopist who visually identifies chrysotile in most samples of talc,' others in Dr. Sellikoff's department 'who have the same mental attitude as Dr. Sellikoff'), Dr. Weissler at FDA ('seems particularly anxious to condemn talc'), and Dr. Lewin, Professor of Analytical Chemistry at New York University who was used as a consultant by FDA ('insists on claiming that asbestos is present in talc found to be free of asbestos by other authorities'). Plaintiff's Exhibit 2514, JNJNL61_000016437.

O. JNJ continues to mislead the public via their website www.factsabouttalc.com

239. The current JNJ website "Facts about Talc" states in part:

239.1. "We continue to use talc in our products because decades of science have reaffirmed its safety. Your trust in Johnson's Baby Products and your confidence using them every day is a huge responsibility – that's why we only use ingredients that are deemed safe to use by the latest science. Research, clinical evidence and over 40 years of studies by medical experts around the world continue to support the safety of cosmetic talc. Health authorities around the world have reviewed the data on talc, and it is used widely across the globe.

239.2. "Even with talc's long history of safe use in consumer products, some have questioned whether using talcum powder can increase a person's risk of developing cancer. Recently, there have been questions raised as to whether the talc used in consumer products is

contaminated with asbestos. The weight of the science does not support any claim that our talc products cause cancer.

239.3. "Thousands of tests repeatedly confirm that our consumer talc products do not contain asbestos. Our talc comes from ore sources confirmed to meet our stringent specifications. Not only is our talc routinely tested to ensure it does not contain asbestos, our talc has also been tested and confirmed to be asbestos-free by a range of independent laboratories and universities."[74]

240. In contrast, FDA's website about Talc states in part:

240.1. "Published scientific literature going back to the 1960s has suggested a possible association between the use of powders containing talc in the genital area and the incidence of ovarian cancer. However, these studies have not conclusively demonstrated such a link, or if such a link existed, what risk factors might be involved.

240.2. "Cosmetics must be properly labeled, and they must be safe for use by consumers under labeled or customary conditions of use. The law does not require cosmetic companies to share safety information with FDA.

240.3. "Both talc and asbestos are naturally occurring minerals that may be found in close proximity in the earth. Unlike talc, however, asbestos is a known carcinogen when inhaled. There is the potential for contamination of talc with asbestos.

240.4. "In addition, questions about the potential contamination of talc with asbestos have been raised since the 1970s."[75]

241. In my opinion, JNJ continues to mislead the public on its website factsabouttalc.com.

[74]Johnson & Johnson Consumer Inc., *Facts About Talc*, https://www.factsabouttalc.com/ (last visited November 13, 2023).
[75] U.S. Food & Drug Administration, *Talc*, https://www.fda.gov/cosmetics/cosmetic-ingredients/talc (last visited November 13, 2023).

P. Conclusion

242. In my opinion, although controversies and complexities existed, JNJ defended its product despite significant questions regarding its safety and put the public at risk.

VII. JNJ had an available alternative to talcum powder in cornstarch and had evidence of that in the 1970's

243. In a 1964 memo with subject "Cornstarch Development" reported a meeting with JNJ's W. H. Ashton, R.G. Schoel, and others, Dr. Ashton writes:

243.1. "Mr. Schoel requested we immediately undertake the formulation and development of a cornstarch product which is inexpensive and free-flowing.

243.2. "The product will use our standard perfume, P-5. It will be compounded at a level which gives an aroma match to our standard talc article.

243.3. "The raw material cost of the Staley product is estimated to be 6.7 cents/lb. of product plus perfume."

243.4. Of the cornstarch products considered, "the Dry Flo has very appealing tone because it would open the door to a merchandising advantage which could refer to an all starch product, i.e. a blend of it with U.S.P. Cornstarch would have no inorganics.

243.5. One of the largest commercial uses of Dry Flo was "as a condom lubricant where it replaced talc because it was found to be absorbed safely in the vagina whereas, of course, talc was not. JNJ 000265536-38.

244. A Johnson & Johnson research proposal written by W. Ashton, dated March 5, 1974, and titled "TALC ALTERNATIVES" stated:

244.1. "During the past couple of years our need for a non-talc dusting powder base has increased as a direct results of the talc/asbestos controversy. The thrust against talc has centered

primarily on biological problems alleged to result from the inhalation of talc and related mineral problems.

244.2. "For defensive reasons, in the event that talc must be removed from the market, the development of a product based on ordinary cornstarch (Formula 31) is being finalized.

244.3. "The product concept is that Formula 31 is divorced from talc allegations since cornstarch is a non-mineral. The assumption is that Formula 31 will be non-reactive (i.e., biodegradable) . . ." JNJNL61_000001954-66.

245. In JNJ's Corn Starch Powder Fact Book dated 1976, the research and development of the cornstarch baby powder was described:

245.1. "The first development period which took place between February 1964 to March 1968 was centered on producing a medicated corn starch baby powder. JNJTALC000866115.

245.2. It continued, "During the second phase of development which began in July 1971 and is active presently, the effort was directed at duplicating Johnson's Baby Powder (talc) with a biodegradable powder either as a replacement in even[sic] of a crisis or as an extension product. JNJTALC000866116.

245.3. "The properties of corn starch and other powders did not duplicate those of talc but had unique and desired properties of their own. Corn Starch Baby Powder is more absorbent, whiter, more flowable, apparently able to retain perfume better than the talc products. It is lubricious but has a different texture than talc." JNJTALC000866116.

245.4. "Human and animal studies were found to be satisfactory." JNJTALC000866116.

245.5. "Johnson's Corn Starch labeled as such was preferred over Johnson's Baby Powder by 62% to 30%. The Corn Starch powder was preferred for its effectiveness, curative and other properties related to corn starch, i.e., absorption." JNJTALC000866117.

245.6. "The data supports the conclusion that cornstarch is less reactive than talc and that there was a progressive loss of starch from the tissue with time. This latter observation would suggest that the accidental inhalation of cornstarch powder will not result in any chronic harmful effects." JNJTALC000866125.

245.7. The "Estimated Release Date" is written as "August 1976." JNJTALC000866104.

246. In 1978, the FDA determined that "corn starch is safe and effective for OTC use as a skin protectant." JNJ000348778; Department of Health, Education, and Welfare, Food and Drug Administration, Skin Protectant Drug Products for Over-The-Counter Human Use, Conditions for Safety, Effectiveness and Labeling; Proposed Rulemaking. August 4, 1978, Part II.

247. A July 18, 1977, JNJ review with the subject "JOHNSON'S Baby Powder with Cornstarch U/A Analysis" to C.E. LaRosa from Lauren E. Hielle-Tucker states: "In view of possible government legislation banning the cosmetic use of talcum powder, the Brand is test marketing JOHNSON'S Baby Powder with Corn Starch in Ft. Wayne, Indiana as a possible product replacement formula." JNJ 0002456.

248. In 1984, A document titled "Johnson & Johnson Baby Powder: Questions and Answers," was "developed for limited internal distribution in response to the need for clarification of issues relating to baby powder and talc." JNJ 000011150. This document states:

248.1. "Specifically, its sole purpose at this time is to provide designated company spokespersons with answers to questions which could be raised by the press. It is not meant for distribution to anyone other than the individuals who will act as company spokespersons as necessary." Three executives are mentioned, including James Utaski, President of JNJ's Baby Products Company. JNJ 000011151.

248.2. "Communication objectives are: 1) Johnson & Johnson Baby Powder, used properly, is safe. Extensive, scientifically documented evidence supports this claim as does the Food and Drug Administration (FDA), and 2) No one knows more about safe, high quality baby care than Johnson & Johnson Baby Products Company. To ensure continued confidence in our baby powder, we will conduct research as needed to reconfirm the safety of the product." JNJ 000011152.

248.3. Examples of Q&A included:

> "Q: Haven't they found traces of asbestos in talcum powder?
>
> A: Not in JOHNSON'S Baby Powder. Since the 1940's, when the testing technology first became available, Johnson & Johnson has regularly tested its talc to insure no asbestos contamination. Years ago, before quality controls were in place, some talcum powders could have contained asbestiform particles. Since 1976, however, the FDA has been conducting tests on a regular basis and has declared all talc-based baby powders to be free of such particles.
>
> Q: Why did you introduce a cornstarch product?
>
> A: While talc provides a moisture repellent barrier on the skin, cornstarch absorbs moisture to make skin feel dry. It was found that some consumers preferred it, and we wanted to provide them with a superior cosmetic grade cornstarch.
>
> Q: Isn't it because it is safer?
>
> A: Not at all. First, the safety of talcum powder has been continuously re-affirmed by Johnson & Johnson, the medical community and by the government. And, we are always conducting research to ensure its safety. JNJ 000011156, JNJ 000011185.

249. In 2000, a review article, published in the American Journal of Obstetrics and Gynecology and titled "Perineal application of talc and cornstarch powders: valuation of ovarian cancer risk" addressed these issues and concluded:

249.1. "In contrast to talc, cornstarch contains no asbestos and is capable of being removed from the peritoneal cavity, as demonstrated by in vivo studies on granuloma formation.

249.2. "In view of the chemical nature of cornstarch, an increased risk for ovarian cancer as a result of perineal exposure to cornstarch, is biologically implausible. Furthermore, epidemiologic studies have found no association between perineal application of exclusively cornstarch powders and ovarian cancer.

249.3. "Consequently, no increased risk for ovarian cancer from the use of perineal powder containing cornstarch exclusively is predicted from the review of the available literature." JNJ000018894, Whysner John and Mohan, Melissa. Am J Obstet Gynecol 182(3).

250. As noted above, in my opinion, confronted by the laboratory, geological and epidemiological evidence in its possession, a reasonable and prudent company would reformulate the product or stop selling it. JNJ had evidence in its possession that cornstarch was a safe and effective replacement for talc. The failure to switch to cornstarch put the public at risk.

VIII. JNJ BABY POWDER LABEL AND LABELING WAS FALSE AND MISLEADING

250.1. Over decades, JNJ Baby Powder made claims that it was "clinically and scientifically proven," "mild and gentle," "pure," "purest, mildest, gentlest," and "most effective." JNJ 000364540.

251. Over time, JNJ's Baby Powder made the claims that "Johnson's the Number 1 choice of hospitals." JNJ 000108692.

252. JNJ for decades built an image that it associated with its products "enhancing bond between mom and baby" and "most trusted by parents and health care professionals." JNJTALC000733349.

253. "That trust" was used within the company as its major asset and "golden egg." JNJ 000364540.

254. Key to JNJ's corporate strategy was an image of trust that grew out of the mother and child bond.

255. A JNJ PowerPoint presentation titled "EQUITY," prepared by Vice President of Global Marketing Marco Cirillo for "Baby Camp," stated:

255.1. "Agenda: Why is Baby the corporation's #1 asset? [JNJ] is a name. [JNJ] is a logo. [JNJ] is a brand of products. [JNJ] is a manufacturer of branded products. [JNJ] is a large healthcare company. [JNJ] is a parent company. [JNJ] is more than that. It is a complex sum of meanings, associations, values and feelings. [JNJ] is deeply linked to baby products."

255.2. A Healthcare Corporate Identity Study by Yankelovich Partners in 1995 showed 88% of consumers linked Johnson & Johnson to "baby products".

255.3. An Emotional Bonding Study, comparing Johnson & Johnson with competitors, from 1995 associated Johnson & Johnson (Johnson's) baby care with trust (72%) and safety (75%).

255.4. "Trust is important for healthcare companies." According to a Johnson & Johnson Corporate Equity Study in 1996, 95% of consumers and healthcare professionals both stated that trust is "Extremely/very important".

255.5. From the 1996 Johnson & Johnson Architecture Study, "What is 'Trust' in healthcare?: Products that **will work** without any **unexpected adverse** physical/emotional **effects.**" [emphasis in original]

255.6. "What is 'Trust' in healthcare?": Consumers depend on the company to make products that are "effective" and "will not harm".

255.7. "Johnson & Johnson has: 'Deep, Personal Trust.'"

255.8. A 1996 Johnson & Johnson Architecture Study, "Deep, Personal Trust" based on being "safe" ("Won't hurt me") and "personal" ("'Familiar' intimacy with the Company").

255.9. "Johnson & Johnson's unique trust results in real business gains for the company." The slide gives the following examples of public tendencies: "Consumers: Forgive "brand" crisis. Institution: More interested in, willingness to work with, ability to consider ideas from. Partners: Predisposition for likeability, credibility and authority."

255.10. "What does the Johnson's Baby brand stand for?" JNJ lists "Safe," "Mild," "Pure," "Gentle," . . . "Effective," "Appealing in use," "Trustworthy," "Wholesome" . . . "Caring" and "Warm."

255.11. JNJ summarizes their presentation by stating: "(1) Baby is the corporation's #1 asset and the mother-infant bond is at its core; (2) Johnson's baby is 50% heart and 50% mind; (3) We MUST protect and enhance the Baby Equity." JNJTALCC000354984.

256. In my opinion the words JNJ used to market its baby powder created an impression that the company had substantiated the safety and purity of its product. That was false and misleading.

IX. SUMMARY OF OPINIONS[76]

In my opinion:

1. Of all the products that fall under FDA's jurisdiction, cosmetics are among the least regulated. This is reflected in the fact that there is no premarket approval of cosmetic products.
2. A cosmetic manufacturer has a responsibility to substantiate the safety of their product or must warn consumers that the safety of their product has not been determined or not sell their product.
3. If a health hazard may be associated with the product, a cosmetic manufacturer must include a warning on their product.
4. The federal regulation of cosmetics is less stringent than the regulation of drugs, medical devices, and food additives. FDA's oversight of cosmetics is also limited by resource constraints.
5. Consistent with FDA regulations and statutes, a cosmetic manufacturer under the cosmetic industry standards must assure the safety of their ingredients. It is the responsibility of the cosmetic manufacturer to assure that there is reasonable certainty in the judgment of competent scientists that the product is safe.
6. Manufacturers have a responsibility to assure that there is reasonable certainty there is no evidence to suspect their cosmetic may pose harm.
7. If there is evidence that there are reasonable grounds to suspect that the cosmetic product may pose harm for the proposed conditions of use, such product does not meet the

[76] This list of opinions is not exclusive. For all opinions, please see entire report.

industry standards for safety.

8. Once JNJ had evidence of a) the presence of asbestos because of its known carcinogenicity and absence of a threshold dose; or b) the presence of non-asbestiform amphiboles or fibrous talc, the safety of their product was not established.

9. Beginning in the 1970's, the safety of JNJ's talcum powder products had not been substantiated, consumers were not warned of potential health risks, and there was a reasonable basis to believe that such an association between the product and health risks.

10. Beginning in the 1970's, because the safety of their product was not established, their talcum powder products should not have been sold.

11. The safety of nonasbestiform amphibole or cleavage fragments was and has not been established.

12. Determination by a laboratory that certain amphibole particles were nonasbestiform in nature does not mean the safety of those nonasbestiform amphiboles was substantiated.

13. The controversies and/or complexities surrounding: 1) the definition of asbestos; 2) what was excluded from the definition of asbestos; 3) the geologic relationship between asbestos and talc; 4) the inability of laboratory tests to characterize individual amphibole fibers as asbestiform or non-asbestiform; 5) whether cleavage fragments of similar dimensions to asbestiform fibers pose similar risks; 6) the ability to distinguish between asbestiform and cleavage fragments; 7) the limitations of detection by various laboratory measurements; 8) epidemiological results; 9) the inability over the decades of FDA to arrive at a definitive testing method for asbestos in talc; 10) the significance of talc fibers; and 11) the extent and routes of exposure, reinforce the conclusion that the safety of the product had not been established.

14. Unable to substantiate the safety of their talcum powder products, JNJ was required to place the following conspicuous statement on the principal display panel: "Warning-The safety of this product has not been determined." 21 CFR §740.10.

15. Based on the totality of evidence, JNJ's findings and notice of naturally occurring mineral silicate fibers of the serpentine and amphibole series including, but not limited to, tremolite fibers, actinolite fibers, anthophyllite fibers, amphibole asbestos, chrysotile (serpentine asbestos), fibrous talc and non-asbestiform amphibole in talc samples prohibited JNJ from selling JNJ talcum powder products because they contained poisonous and deleterious substances, which "may render" the products "injurious to users under the conditions of use described in the labeling thereof or under such conditions of use as are customary or usual . . . ," and were therefore adulterated. 21 U.S.C. §361.

16. Based on the totality of evidence, at a minimum, Johnson & Johnson's findings and notice of naturally occurring mineral silicate fibers of the serpentine and amphibole series including, but not limited to, tremolite fibers, amphibole asbestos, chrysotile (serpentine asbestos), fibrous talc and non-asbestiform amphibole in talc samples prohibited the company from determining that the safety of Johnson & Johnson talcum powder products had been substantiated.

17. In light of a) the FDA's 2014 petition response acknowledging that there remains some evidence to suspect or question the safety of talcum powder products, b) the totality of the medical literature since 2014 that continues to raise safety questions; and c) IARC's classification, defendants failed to substantiate the safety of their talcum powder products.

18. JNJ decided in the 1970's to aggressively defend its product. That strategy kept their product on the market for fifty years but put the public's health at risk. It need not have been that way if JNJ was willing to bear any additional cost and reformulate the product.
19. A reasonable and prudent company, would have reformulated the product in the 1970's.
20. JNJ through CTFA created the impression beginning in 1976 that changes in testing resolved the asbestos controversy in talc.
21. The problems with the CTFA testing methodology J4-1 were: 1) it did not address chrysotile; 2) it had some very significant detection limits because it did not include transmission electron microscopy; 3) it was not accompanied by any changes in mining or manufacturing which made the product safer; 4) and it failed to report fibrous talc. The repeated assertion by JNJ that there have never been any positive tests for asbestiform particles indicates that the CTFA testing methodology J4-1 did not accomplish anything.
22. The acceptance of JNJ's concept that changes in testing resolved the asbestos controversy in talc by researchers and health agencies impeded the resolution of important safety issues.
23. JNJ defended its product by representing that there could be safe levels of asbestos when there was no known threshold and put the public at risk because there is no known safe level of asbestos.
24. In light of the fact that asbestos was a known carcinogen with no known threshold, a reasonable and prudent company would attempt to improve the sensitivity of its testing so as not to put the public at risk.

25. Making claims that its product was asbestos free without vigorous efforts to improve the sensitivity of the testing methods is concerning.
26. Opposing efforts to improve the sensitivity of the testing methods is evidence that JNJ defended its powder while putting the public at risk.
27. For more than fifty years JNJ made representations that were misleading and not transparent.
28. Confronted by the laboratory, geological and epidemiological evidence in its possession, the only prudent and reasonable option was to reformulate the product or stop selling it.
29. In light of the totality of evidence in JNJ's possession regarding scientific evidence of the association of talcum powder and ovarian cancer, laboratory testing suggesting the presence of particles for which the safety was not established, and the complexities of the geologic formation of talc and asbestos, JNJ's statements to the gynecologic oncologists and the medical community more broadly were misleading because they failed to tell the whole story.
30. JNJ, by adopting the approach to the asbestos issue in talc, which was to initiate studies only as required by confrontation, failed to substantiate the safety of its product.
31. In light of the fact that JNJ had evidence that (a) its existing methodologies could produce false negatives that would fail to identify asbestos particles when they were present, and (b) the asbestos was a carcinogen for which there was no known safe exposure, JNJ had a responsibility to take all feasible steps to develop either a methodology that reduced the amount of false negatives as low as reasonably possible or to stop selling the talc product.
32. There is evidence that the opportunity for bias was introduced into the asbestos testing programs.

33. A reasonable and prudent manufacturer, when confronted with a carcinogen for which there is no known human threshold, would adopt procedures that were most protective (i.e. "conservative") of the public health, even at the risk of increased variability.

34. While microscopists and geologists have much to add to our scientific understanding, the failure to adopt a public health approach to asbestos in talc testing, even if that led to over-inclusion and false positives, put consumers at risk.

35. In dealing with a known carcinogen, the test methods that are employed should use a level of detection that does not miss finding asbestos fibers that are present in the sample, taking into account the mean background level. The test methods should be sensitive enough to protect the public health.

36. JNJ's failure to recognize and mitigate the potential risks of fibrous talc put the public at risk.

37. JNJ's defensive strategy of creating doubt and confusion failed to resolve the safety issues associated with its product.

38. JNJ continues to mislead the public on its website factsabouttalc.com.

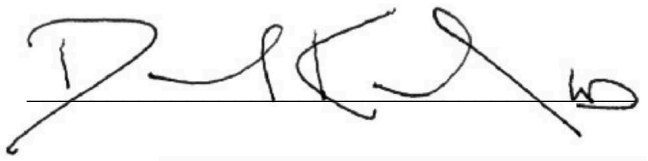
39. JNJ failed to report to the FDA that laboratory tests found evidence of naturally occurring mineral silicate fibers of the serpentine and amphibole series. That failure misled the FDA over the last half a century.

40. JNJ's representation to the FDA in their March 17, 2016, letter that no asbestos-form structures have ever been found during any testing was false and misleading.

41. Although controversies and complexities existed, JNJ defended its product despite significant questions regarding its safety and put the public at risk.

42. Confronted by the laboratory, geological and epidemiological evidence in its possession, a reasonable and prudent company would reformulate the product or stop selling it. JNJ had evidence in its possession that cornstarch was a safe and effective replacement for talc. The failure to switch to cornstarch put the public at risk.

November 15, 2023



SCHEDULE I: EPIDEMIOLOGICAL LITERATURE TABLE

I. COHORT STUDIES

AUTHOR	STUDY DESCRIPTION	FINDINGS	LIMITATIONS	DISCUSSION AND CONCLUSIONS
Gertig (2000) Gates (2008) Gates (2010)	Cohort Study (Nurses' Health Study "NHS") Study of 121,700 registered nurses between ages 30-55 years from across US. Talc use determined by self-administered 1982 questionnaire. Asked women if they had ever commonly used talcum, baby powder, or deodorizing powder on their perineal. Possible responses were: no, daily, 1-6 times per week, or < 1/week. Also asked if they had applied products to sanitary napkins. "Ever talc use" classified as ever talc use on either perineal area or sanitary napkins. Every two years, participants reported health updates; no updates on talc use were included, but self-reported cases of ovarian cancer were adjudicated through medical record reviews. Exclusions for incomplete questionnaires on talc, if reported both ovaries removed, if reported a hysterectomy but did not report whether at least one ovary remaining, or history of radiation therapy. Three publications resulted from this study. The first, published in 2000, included 78,630 women, of whom 307 cases of ovarian cancer were diagnosed. Ever	**2000 (1st Report):** •Ever Talc Use – R.R. 1.09 (0.86 – 1.37) •Invasive Serous Ovarian Cancer – R.R. 1.40 (1.02 – 1.91) **Gates 2008 Follow-up (2nd):** •Epithelial OC = 1.36 (1.14 – 1.63) •Serous OC = 1.60 (1.26 – 2.02) **Gates 2010 Follow-up (3rd):** •Results not statistically significant for talc exposure •All epithelial = 1.06 (0.89 – 1.28) •Serous = 1.06 (0.84 – 1.35)	**OVERALL** The questions on talcum powder use referred to ever use and cannot determine the age at which women began using talc or the duration. Relatively short follow-up. Tubal ligation questions asked as part of contraception. **2010 (2nd Follow-up)** • Extended the follow up through 2006 but no updated use or exposure data	**2000:** Prospective Study No overall association between "ever use" of talcum powder and total risk for ovarian cancer (R.R. 1.09; 95% CI .86 – 1.37) 40% Increased risk for serous invasive cancer with any (ever) history of talc use which comprises the majority of ovarian cancer (R.R. 1.40; 95% CI 1.02 -1.9) Risk stratified by histologic sub-type There was no apparent dose response, although lacked information on duration of use. **2008:** •Regular talc use was associated with increased ovarian cancer risk in the combined study population (RR, 1.36; 95% CI, 1.14-1.63; Ptrend < 0.001). may have a higher risk of ovarian cancer associated with genital talc use. These results provided additional support for a main effect of genital talc exposure on risk of epithelial ovarian cancer. The presence of a significant trend between frequency of talc use and risk of total and serous invasive ovarian cancer in the NECC and pooled analysis further strengthens the evidence for an association, as most previous studies have not observed a dose-response

AUTHOR	STUDY DESCRIPTION	FINDINGS	LIMITATIONS	DISCUSSION AND CONCLUSIONS
	use of talc was reported by 40.4% of the cohort; 14.5% ever used talc daily. The second report from the Nurses' Health Study was in 2008. This was a pooled analysis post-NHS: 2 phases (1992-1997; 1998-2003). Results from the Nurses' Health Study were combined with other cases and controls from case-control studies. Study updated talc analysis from NHS, including 8 additional years of follow-up. Analysis included 1,175 cases and 1,202 controls from a New England-based case-control study and 210 cases and 600 controls from the prospective Nurses' Health Study. Additional support for the presence of a significant trend between the frequency of talc use and risk of total and serous ovarian cancer The third Nurses' Health Study report was published in 2010. This analysis included women from two separate cohorts; the exact numbers of women and cases with exposure data regarding talc was not specified.			with increasing frequency or duration of talc use. Inflammatory response in vivo In vitro study where cells undergo cell proliferation, neoplastic transformation and cellular generation of reactive oxygen species increasing with increased exposure to talc. Although no prior studies have examined gene-talc interactions, the indication of a possible immune-related mechanism between talc and ovarian carcinogenesis and the evidence for gene-asbestos interactions suggest that genes involved in detoxification and inflammatory pathways could be important in the response to talc. **2010** The incomplete data for a few exposures, in particular talc use and family history of ovarian cancer, also are weaknesses because the limited data may have influenced the observed associations for these exposures. The association with talc use in our analysis differed from the association in a previous analysis of the NHS cohort (34), possibly because of a greater degree of exposure misclassification over 24 years of followup. However, the suggestive positive association with the mucinous subtype may reflect a longer latency period between talc

AUTHOR	STUDY DESCRIPTION	FINDINGS	LIMITATIONS	DISCUSSION AND CONCLUSIONS
				exposure and development of mucinous tumors. Finally, the use of a single summary measure for certain exposures, such as physical activity, also may have limited our ability to detect an association. Associations differ by subtype.
Houghton (2014)	Cohort Study (Women's Health Initiative) • Enrolled 93,676 women between 1993-1998 • 61,576 post-menopausal participants in the study cohort • 429 total ovarian cancer cases • Average age at time completed questionnaire of talc use 62-63.3 • Follow up for disease ascertainment was a mean of 12.4 years • Included post-menopausal women between 50 & 79 • Talc use assessed at baseline with self-reporting questionnaires	• Use of genital powders for >20 years resulted in a RR 1.06, 95% CI (0.87-1.28) • Risk of serous invasive cancer was increased by a non-statistically significant 13% (hazard ratio 1.13, 95% CI 0.84 - 1.51).	Asked about duration of use only. The study may have been comparing long-term infrequent users with short term frequent users. Lack of information regarding oophorectomy after baseline Non-differential misclassification (need to recall past use and duration); leading to a bias toward the null Information on use was not collected after baseline. Assumed women remained in same exposure group for 12 years Information of powder use not collected after baseline Short follow-up period (12.4 years) Obtained information on duration of use via interviews, but unknown during which years powder used (i.e. application on genital area, sanitary napkins and diaphragm)	Ever perineal powder use was not associated with ovarian cancer risk, nor was it associated with ovarian cancer when assess by area of application, duration of use, or ovarian cancer subtype.

AUTHOR	STUDY DESCRIPTION	FINDINGS	LIMITATIONS	DISCUSSION AND CONCLUSIONS
			Queried general powder use rather than talc powder and had no specific information regarding the content of talc in products used.	
Gonzalez (2016)	Cohort Study (Sister Study) The Sister Study, launched in 2003, enrolled 50,884 women who had a sister diagnosed with breast cancer Participants included 154 exposed cases with ovarian cancer who did not have diagnosis of breast cancer but sister had breast cancer Enrollees were ages 35-74 years At baseline, participants asked about talc and douching use during the previous 12 months 52% menopausal	•Talc - H.R. 0.73 (0.44 – 1.2) •Douching – O.R. 2.1 (2.0 – 2.3)	Not specifically a talc or ovarian cancer study. Baseline questionnaire inquired of douching and talc use during the previous 12 months of study initiation Questionnaire did not inquire about lifetime exposures 37% of cases had no medical records 84% white women; 56% post-menopausal Short follow-up 6.6 years Reported prevalence of talc use was 14%.	Douching, not talc use, associated with increased risk of ovarian cancer

II. CASE CONTROL STUDIES

AUTHOR	STUDY DESCRIPTION	FINDINGS	REPORTED LIMITATIONS	AUTHORS' DISCUSSION AND CONCLUSIONS
Cramer (1982)	Case Control Study. Population based. Evaluated 215 women with epithelial ovarian cancer and 215 age-matched control from greater Boston, MA area. Talc exposure was determined by questionnaire regarding "regular" talc use on the	*Adjusted for parity and menopausal status, any perineal talc exposure reported a relative risk of 1.92 (1.27-2.89) for epithelial ovarian cancer. Women who had regularly engaged in both perineal use and on sanitary napkins had an adjusted relative risk of 3.28 (1.68-6.42) compared to women with neither exposure.*	Potential biases include that menstrual characteristics may differ between women with ovarian cancer and controls. Further since talc into the pelvic cavity is prevented by hysterectomy or tubal ligation inclusion of subjects with pelvic surgery may obviate any association	The argument linking talc and ovarian cancer includes four elements: the chemical relationship between talc and asbestos, asbestos as a cause of pleural and peritoneal mesotheliomas, the possible relation between epithelial ovarian cancers and mesotheliomas, and the

	perineum and/or on sanitary napkins. 42.8% of ovarian cancer patients reported regular use of talc (prior to developing ovarian cancer) compared to 28.4% of controls.		between talc and ovarian cancer. Other confounders include potential for selection bias. Etiology may derive from asbestos content of talc or uniqueness of the ovary which make it susceptible to carcinogenesis from both talc and other particulates. Recall bias is also a potential limitation.	ability of talc to enter the pelvic cavity. The mineral talc is a specific hydrous magnesium silicate chemically related to several asbestos group minerals and occurring in nature with them. Generic "talc" is seldom pure and may be contaminated with asbestos, particularly in powders formulated prior to 1976. This study provides some support for an association between talc and ovarian cancer hypothesized because of the similarity of ovarian cancer to mesotheliomas and the chemical relation of talc to asbestos, a known cause of mesotheliomas.
Hartge (1983) (Letter to the Editor)	Case Control Study. Hospital based. Evaluated 135 women with epithelial ovarian cancer and 171 controls from the Washington, DC area. Talc exposure was ascertained via questionnaire, but the authors did not provide detail as to questions asked.	The authors reported that women who reported any talc use (body powder or diaphragm) had an estimated relative risk of **0.7 (0.4-1.1)**, while use on their genitals had an estimated relative risk of **2.5 (0.70-10.0)** compared with never users.	The analysis was based on only 7 cases and 3 controls. Chance, bias in selection or observation, or confounding may have influenced these estimates. Further, patients with ovarian cancer may have or perceived a greater need for using body powder in the genital area for reasons related to their ovarian cancer or life style.	Data indicate no overall association between all talc use and risk of ovarian cancer. Although a small group of women who specifically reported genital use of body talcum powders showed an excess relative risk, use of talc on a diaphragm, which would be closest to the ovaries, did not seem to elevate risk.
Whittemore (1988)	Case Control Study. Hospital based. Evaluation included 188 ovarian cancer cases and 539 controls in the San Francisco, CA area. *Exposure to talc was determined through structured personal interviews and documented type of use including,*	Women who reported using talcum powder to the perineum showed a relative risk of **1.45 (0.81-2.60).** Use on sanitary pad was associated with a non-statistically significant 38% reduce risk and use on diaphragms was associated with a non-statistically significant 50% increased risk. The relative risk for ovarian cancer increased with increasing applications of talc per	The study results should be interpreted cautiously based on the studies' failure to interview all eligible controls, potential pitfalls in combining two studies and the two control groups in the second study. The is also the possibility of confounding by unmeasured variables.	The data show a trend of increasing risk with increasing frequency of perineal talc exposure, but the trend was not statistically significant. Thus, while these data do not exonerate talc as an ovarian carcinogen, neither do they provide strong evidence to implicate it.

	perineum, sanitary pads, diaphragm or some combination of these uses. Duration of talc use was also ascertained.	month; relative to nonusers, the relative risk for 1-20 times per month was **1.27**, and the relative risk for 20 or more times per month was **1.45**. None of these values was statistically significant. The increased relative risk was apparent for women who had never had tubal ligation or hysterectomy, but not for women who had had one of these procedures. Compared with non-users, women with 1-9 years of use had a relative risk of **1.6 (1.00-2.57),** but women with greater years of use had only a relative risk of **1.11 (0.74-1.65).**		
Booth (1989)	Case Control Study. Hospital based. Evaluated 235 cases with ovarian cancer and 451 controls in the UK. A questionnaire ascertained the frequency of exposure to talc in the genital area (never, rarely, monthly, weekly, daily).	The authors reported women who used talc in the genital area had the following relative risk for ovarian cancer based on the frequency of exposure: Rarely use: **0.9 (0.3-2.4)** Monthly: **0.7 (0.3-1.8)** Weekly: **2.0 (1.3-3.4)** Daily: **1.3 (0.8-1.9)** Cases and controls did not differ by percentage who kept diaphragms in talc.	As the design is case control there may have been some misclassification of controls. The women were not asked how long they had been using talc (duration).	The evidence linking talc with ovarian cancer is controversial. In this study, women who reported talc use in the genital area more than once a week or daily had higher risks of ovarian cancer than women who used talc less frequently. The women were not asked how long they used talc. It is possible that because of their symptoms talc use by the cases may not have reflected their frequency of past use. Since these and other results (Cramer 1982; Hartge 1983) are insufficient to reject an association, further work is need on the relation between genital use of talc and ovarian cancer.
Harlow (1989)	Case Control Study. Population based. Evaluated 116 women with serous or mucinous borderline ovarian cancer identified through a Western Washington	Women who used deodorizing powders had a relative risk of **2.8 (1.1-11.7)** for borderline ovarian tumors, while any perineal exposure to powder showed a relative risk of **1.1 (0.7-2.1)**	The elevated risk among women who specifically used deodorizing powders could have been due to chance or applicable only to borderline, not malignant ovarian tumors.	Given the clues provided by this study regarding the possible importance of deodorizing powders, it would be advisable for future studies to elicit information on brand name of talc-containing powders and the timing and duration of such use. Although

	population-based cancer registry, as well a population-based sample of 158 control women. The study used an open-ended question asking women to specify the types of powder they used for perineal application after bathing, on sanitary napkins, and for diaphragm storage. Powder was categorized as baby powder, deodorizing powder, other/unspecified talcum/dusting powders or as cornstarch.	No data were presented regarding frequency or duration of talc/powder use.		these data need replication, they raise the possibility that the risk of ovarian tumors in women who apply deodorizing powder to the perineum may not relate to talc per se but rather to asbestos contamination and/or a substance or substance used specifically for deodorization. An association between talc use and ovarian neoplasms seems biologically plausible, since particulates contaminating the vaginal area may migrate into the pelvic cavity and since particles of talc have been observed within ovarian tissue.
Chen (1992)	Case Control Study. Population based. Interviewed 112 women with ovarian cancer and 224 community controls in Beijing, China. A questionnaire was developed to obtain histories and data was collected via face-to-face interviews. No information was provided about how women were asked about talc-containing dusting powder product use prior to 3 years before diagnosis (for cases) and a comparable date in controls.	Seven cases and 5 controls reported using "dusting powder" to the lower abdomen and perineum for 3 or more months. After adjusting for education and parity, the users of "talc-containing" dusting powder showed a relative risk of **3.9 (0.9-10.6).**	Given the nature of the cancer registry in China, some of the ovarian cancer patients may not have been ascertained for study. Also, potentially damaging were the high rate of loss due to deaths. A third limitation was the exclusion of controls with current health problems. The small number of subjects of exposed to talc is another limitation.	Similar to previous studies, a threefold increased risk was associated with perineal talc exposure. It is interesting that that similar results are obtained from quite different parts of the world.
Harlow & Cramer (1992)	Case Control Study. Population based. Interviewed *235 white women diagnosed with ovarian cancer in the*	*Perineal talc use was associated with an odds ratio for epithelial ovarian cancer of 1.5 (1.0-2.1) when adjusted for parity, education, marital status, religion, use of*	Authors stated that this study failed to answer a key issue in talc-ovarian cancer association: whether the risk pertains to all cosmetic talc	Because the overall association between genital use of talc and ovarian cancer remains weak, it is unlikely that this exposure-disease pathway is the principal one involved

	Boston, MA metropolitan area. Tumors were confirmed through an independent pathology review. Talc exposure was determined through in-person interviews. Talc use was reported as any genital application, type of application (sanitary napkin/underwear, via partner or application to diaphragm, via dusting to perineum), number of applications per month, years of use, age at first use, years since last use, whether use was before or after 1960, brand of application, estimated total lifetime applications, estimated applications excluding use after hysterectomy or tubal ligation, and estimated applications excluding use after hysterectomy or tubal ligation and use during nonovulatory months.	*sanitary napkins, douching, age, and weight. Direct perineal application showed an odds ratio of 1.7 (1.1-2.7). Use of talc on a daily basis increased the odds ratio for ovarian cancer to 1.8 (1.1-3.0) and use for more than 10 years 1.6 (1.0-2.7). For women who had more than 10,000 applications while menstruating had an odds ratio of 2.8 (1.4-5.4).* *Using techniques of metaanalysis, the authors calculated an OR of 1.3 (1.1-1.6) for any perineal exposure and ovarian cancer risk.*	or only to certain preparations likely to be contaminated with asbestos. The variation in risk among histologic subtypes may reflect a chance finding or a need to examine endometroid and borderline tumors more carefully for evidence of foreign body effect. Authors cannot rule out the possibility of differential over or under reporting of talc exposure their cases and controls, especially in those with reproductive events that enhance ORs. Authors presume that responders and non-responders were similar in characteristics, but validity depends on that presumption. Adjustments were made to account for confounding, but authors cannot rule out the presence of unknown factors might have influenced the observed associations.	in ovarian cancer etiology. The authors concluded that they calculate that by applying these odds ratios to the exposure rate among cases, the proportion of ovarian cancer incidence attributable to this level of talc exposure is about 10%. They further state that given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For that reason, they discouraged the use of talc in genital hygiene, particularly as a daily habit.
Rosenblatt (1992)	Case Control Study. Hospital based. Evaluated a total of 77 cases of ovarian cancer and 46 controls, who were treated for non-gynecologic/non-malignant diseases from Baltimore,	Women who were exposed to genital fibers greater than or equal to 37.4 years had an increased odds ratio for ovarian cancer of **2.4 (1.0-5.8).** Exposure to talc on sanitary napkins resulted in an increase odds ratio of **4.8 (1.3-17.8).** Use of genital bath talc was associated with	Given its small sample size and the potential selection bias stemming from the inclusion of patients from only one hospital, further research needs to be performed in order to confirm the findings.	The authors stated that the results of their study and others suggested that genital fiber exposure may be associated with an adverse effect, but further study is needed to determine if this relationship is causal in nature.

	MD. Participants were interviewed via questionnaire (questions provided in Appendix 1 of publication) about presence and length of genital fiber and respiratory fiber exposure. Fiber exposure was defined as exposure to asbestos, talc, and fiberglass. The "dose" of exposure was determined by adding the number of years of each type of genital or respiratory exposures from all sources. Further, only exposure prior to tubal ligation (for women who had that procedure) was counted.	an odds ratio of **1.7 (0.7-3.9).** Diaphragm use with powder showed an odds ratio of **3.0 (0.8-10.8).** A negative association was observed for antecedent tubal ligation with an odds ratio of **0.15 (0.027-0.88).**		Tubal ligation may protect against ovarian cancer by inhibiting carcinogenic action of talc through blockage of the fallopian tube or through screening effect.
Tzonou (1993)	Case Control Study. Hospital based. Evaluated189 women with ovarian cancer and 200 controls in Greater Athens, Greece area. Exposure was ascertained by asking if women used of talc in the perineal area (no; yes).	After adjusting for variable, talc application in the perineum was associated with a relative risk of **1.05 (0.28-3.98)** based on 6 cases and 7 controls reported using talc in the perineal area.	The study has the power limitation associated with its moderate size and, as in any case-control study, there exists a possibility of selection and, less likely, of information bias. The possibility that ovarian cancer may be caused by exposure to asbestos has be raised by other authors who pointed out that mineral talc is closely related asbestos and presented clinical and experiments evidence linking exposure to talc with ovarian cancer.	The results of the present study do not support an association between talc and ovarian cancer but, given the overlapping range of the confidence intervals, they are not incompatible with it.

Purdie (1995)	Case Control Study. Population based. *Evaluated 824 cases of epithelial ovarian cancer and 860 controls from gynecological oncology treatment centers in three Australian states. Talc exposure was determined through use of a questionnaire via face-to-face interviews.*	*Use of talc around abdomen/perineum was associated increase risk for ovarian cancer with an odds ratio of 1.27 (1.04 - 1.54).*	Selection and recall biases and potential confounders were considered.	Regular use of talc in the region of the abdomen or perineum was associated with a slight increase (and positively associated) in the risk of ovarian cancer.
Cramer (1995)	Case Control Study. Population based. Evaluated 450 women diagnosed with ovarian cancer in Boston, MA area hospitals, and 454 controls selected from the general population. Examined the association between ovarian cancer and prior hysterectomy or tubal ligation.	Use of talc "in genital hygiene" was associated with an increased risk for ovarian cancer with an odds ratio **1.6 (1.2-2.1).**	Authors considered recall bias and confounding	Authors reported a protective effect of prior hysterectomy or tubal ligation for ovarian cancer and offer several explanations including blockage of vaginal contaminants. Thus tubal effluences or vaginal contaminants are no longer able to reach the pelvic cavity and ovaries. Although many vaginal contaminants could be proposed, talc use in genital hygiene may be an important one.
Chang (1997)	Case Control Study. Population based. Evaluated 450 patients with borderline or invasive ovarian cancer and 564 population controls in Ontario, Canada. A questionnaire was used during an in-person interview. Questions about regular talc use and type of talc use, as well as questions from which information about duration and frequency of exposure	Women with any regular talc exposure had an increased risk of developing ovarian cancer with an odds ratio of **1.42 (1.08-1.86).** Use of cornstarch was not associated with increased risk, but there were small numbers in this exposure group. Use of talc on sanitary napkins was associated with an odds ratio of **1.26 (0.81-1.96**), and use of talc after bathing showed an odds ratio of **1.31 (1.00-1.73**). Dose response data revealed an odds ratio per 10 years of use at **1.06 (0.99-1.14).**	Differences in talc concentration among various baby powders, body powders and deodorizing powders were not investigated in this study. Furthermore, reporting error in reported talc use and failure to interview all eligible case and control subjects may have led to biases. As with any case control study, the possibility of selection bias and information bias exists, although the consistency of	This investigation supports previous contentions that exposure to talc may increase risk of ovarian carcinoma. Dusting with talcum powder is not an unusual practice for women and, given the heterogeneity of the etiology and course of ovarian carcinoma, any possible harmful practices, particularly those with little benefit, should be deliberated. A questionable dose-response relationship was observed between duration or frequency of exposure and risk.

	were included. Women were questioned about the application of talc to the perineum and about use of talc on sanitary napkins. They also ascertained the use of cornstarch on the perineum and sanitary napkins.		this study with others that have addressed reproductive factors and ovarian carcinoma is reassuring.	
Green (1997)	Case Control Study. Population based. Included 824 women with ovarian cancer who were identified through cancer registries and 855 population-based controls from 3 Australian states. A Questionnaire was used to determine perineal talc exposure but no details were provided on the specific questions posed regarding talc use. Duration and particular ages/years used were also obtained.	Women who had ever used talc in the perineal region had an increased risk for ovarian cancer with a relative risk **1.3 (1.1-1.6).** Further the authors found that compared with women who had neither used talc nor had surgical sterilization, risk was highest among talc users without surgery with a relative risk **1.3 (1.0-1.7)** and lowest among women with a history or tubal sterilization or hysterectomy who had not applied talc to the perineum with a relative risk **0.6 (0.5-0.84).**	Recall of use of talc among older women may not have been accurate, tending to reduce the estimated RRs; moreover, the actual quantity of talc used was unknown.	Despite the limitation, these results add support to the body of evidence implicating talc as a factor in the pathogenesis of peritoneal epithelial neoplasia. Our findings support the theory that contaminants from the vagina, such as talc,… gain access to the peritoneal cavity through patent fallopian tubes and may enhance malignant transformation of the ovarian surface epithelium. Surgical tubal occlusion may reduce the risk of ovarian cancer by preventing the access of such agents. In view of this particular finding (reduction of risk of ovarian and peritoneal tumors) and the evidence presented here and elsewhere that pelvic contaminants such as talc are associated with ovarian cancer, we conclude that closure of the fallopian tubes by surgery prevents chronic contact between these agents and ovarian epithelium. It seem likely that peritoneal irritants act as co-carcinogens by increasing the accumulated number of mutational events in ovarian surface epithelial cells.

Cook (1997)	Case Control Study. Population based. Evaluated 313 cases of ovarian cancer identified through a cancer registry and 422 population-based controls in Western Washington. Women were questioned about storing diaphragms in powder, dusting perineal areas with powder after bathing, powdering sanitary napkins, and using genital deodorant sprays. Women were also questioned about duration and frequency of powder application and about types of powder applied.	Use of any of the genital powder applications (perineal application, sanitary napkins, genital deodorant sprays, diaphragms resulted in a relative risk **1.5 (1.1-2.0).** The risk was highest in women who dusted perineal areas with powder, with a relative risk **1.8 (1.2-2.9).** Compared with never users of genital deodorant sprays, women who used these products for 12 months or less had a relative risk for ovarian cancer of **1.5**, while those who used them for more than 12 months had a relative risk of **2.7**. Compared with never users of genital deodorant sprays, women who used an estimated 500 lifetime applications or less of genital deodorant sprays had a relative risk for ovarian cancer of **1.7**, while those who had an estimated lifetime applications greater than 500 had a relative risk of **2.6.** Both of these dose-response trends were statistically significant ($p < 0.05$). None of the other types of perineal talcum powder product use showed trends to greater risk with greater estimated duration used or applications. The authors then categorized powders into specific types: cornstarch, talcum powder, baby powder, deodorant powder, and scented body/bath powder (assuming talcum powder was likely a constituent of the latter three as well). Exclusive use of cornstarch only or of deodorizing powder only were associated with no increase in risk for ovarian cancer, but the	Study reported that it is difficult to postulate that an increased risk for ovarian cancer may specifically be due to powder and associated constituents when some of the deodorant sprays do not contain aerosolized powder. Limitations of the present study include the fairly low proportion of eligible women who participated and the potential differential recall of powder usage.	These results offer support for the hypothesis, raised by prior epidemiologic studies, that powder exposure from perineal dusting contributes to the development of ovarian cancer. Given the common practice (28-51% of women), even the modest elevation in ovarian cancer risk by most epidemiological studies could have a notable impact on the incidence of ovarian cancer in the US.

		numbers of cases were very small (5 and 9, respectively). Exclusive use of other types of powder increased risk between 20 and 60 percent, but the results were not statistically significant. Risk for serous ovarian cancers increased in women who ever used any genital powder with a relative risk **1.7 (1.1-2.5).** The relative risk for "other tumors" among ever users was **1.8 (1.1-2.8),** while risks for mucinous or endometrioid tumors were not increased in genital powder users.		
Godard (1998)	Case Control Study. Population based. Evaluated 170 women with ovarian carcinomas or borderline tumors and 170 controls in Montreal, Canada. The authors used questionnaires, but talc use questions were not described in the publication. However, the variable of "ever" versus "never" perineal use of talc was reported.	Women who had ever used perineal talc had an increased risk for ovarian cancer with a relative risk **2.49 (0.94-6.58).** The relative risk for sporadic ovarian cancer **2.45 (0.85-7.07),** and a relative risk of **3.25 (0.85-12.4)** for familial ovarian cancer.		Perineal talc used was a nonsignificant risk factor (RR 2.49, P=.064). Talc has previously been implicated in the development of ovarian cancer. Although there are reports of talc embedded in human ovarian tissue and of talc migrating through the human female reproductive tract, the literature reviewed does not provide any convincing evidence that pure cosmetic talc, when used as intended, presents a health risk to women.
Wong (1999)	Case Control Study. Hospital based. Evaluated 499 patients with ovarian cancer and 755 patients with non-gynecological malignancies in Buffalo, NY. Exposure to talc was determined using a self-	Women with ever use of talc in genital or thigh region had an odds ratio of **1.0 (0.8-1.3)** and both talc applied to those region and sanitary napkin has an odds ratio of **1.1 (0.7-1.7).** For duration of use of talc, a use of 1-9 years reported an odds ratio of **0.9 (0.6-1.5**); 10-19 years at	The study has two potential weaknesses. First, as with any retrospective study using data collected from the patients' recall of evens, potential ascertainment and recall bias may exist. Second, condoms and diaphragms are potential sources of talc	A significant association between the use of talcum powder and the risk of developing epithelial ovarian cancer is not demonstrable, even with prolonged exposure.

	administered questionnaire. Women were queried on site of talc use (sanitary napkin vs. genital/thigh area) and duration of use. But, the study did not report the questions asked.	**1.4 (0.9-2.2)** and greater than or equal to 20 years of **0.9 (0.6-1.2).**	exposure. The questionnaire asked about these forms of contraception but does not ask about the frequency or duration of usage. Consequently, the study is limited to the use of talc on the perineum or sanitary napkins and does not address potential talc exposure from condom or diaphragm use.	
Cramer (1999)	Case Control Study. Population based. Evaluated 563 women with ovarian cancer and 523 controls in eastern MA and NH areas. Exposure to body powders was ascertained through personal interview. Women were asked if they had "regularly used talc, baby or deodorizing powders dusted or sprayed" to feet, arms, or other non-genital areas, to the genital or rectal area, on sanitary napkins or on underwear. A husband's use of powder in his genital area was also assessed. Age at first use, types of powders, applications per month and total years of use were assessed. Potential exposure from condoms or diaphragms was not assessed.	Women with any genital exposure had an adjusted odds ratio of **1.60 (1.18-2.15).** For frequency per month, women with less use less than 30 had an odds ratio of **2.21 (1.37-3.56)** whereas with 40+ use had an odds ratio of **1.57 (0.8-3.10).** Women with serous invasive ovarian cancer had an adjusted odds ratio of **1.7 (1.22-2.39)**	The relatively weak odds ratios observed could reflect potential biases, especially recall and confounding. Recall bias is possible because talc exposure in these studies is based on person recollection. However, recall bias seems more likely to affect exposures that have occurred over a short term than those that have occurred over long term. If publicity regarding the association correlated with selective recall, one might expect a trend for cases from more recent studies to report higher exposure rate. As to confounding, the authors found no evidence that genital talc exposure varied by key risk factors for ovarian cancer such as age, parity, OC use. The demonstrated consistent association between talc and ovarian cancer appears to be	In summary, we have demonstrated a consistent association between talc and ovarian cancer that appears unlikely to be explained by recall or confounding. The dose-response relationship is weak but improved by considering factors such as closure of the female tract, ovulation and exposure prior to pregnancy, and we have outlined a plausible biologic rationale for this association. We estimate that avoidance of talc in genital hygiene might reduce the occurrence of a highly lethal form of cancer by at least 10%. Balanced against what are primarily aesthetic reasons for using talc in genital hygiene, the risk benefit decision is not complex. Appropriate warnings should be provided to women about the potential risks of regular use of talc in the genital area.

			unlikely to be explained by recall or confounding. In attempting to address the lack of a clear dose response, the authors point out that it is difficult to quantify the amount of powder actually used and degree of perineal dusting that might constitute an "application of talc," Other considerations include the use during ovulation and closure of tract as a result of tubal ligation or hysterectomy.	
Ness (2000)	Case Control Study. Hospital based. Evaluated women with ovarian cancer ascertained from 39 hospitals in Eastern Pennsylvania, Southern New Jersey, and Delaware. 767 cases of ovarian cancer were interviewed, with 1,367 population-based controls. Talc exposure was determined by asking women if they ever used talc, baby, or deodorizing powder at least once per month for 6 or more months in their genital or rectal area, on sanitary napkins, on underwear, on a diaphragm or cervical cap, or on non-genital areas. They also were asked about male partner	Compared with never-users, women who used talc in genital/rectal areas had an elevated odds ratio for ovarian cancer of **1.5 (1.1-2.0).** Users on sanitary napkins had an increased risk for ovarian cancer with an odds ratio **1.6 (1.1-2.3).** Use on underwear increased risk to an odds ratio of **1.7 (1.2-2.4).** Use on a diaphragm/cervical cap or by a male partner did not increase risk. Among those who used in the genital/rectal or other body areas did not show increasing risk with increasing numbers of years of use.	A limitation of the study was the somewhat low participation rate among cases and controls. Another limitation is the potential for recall bias, which is a concern with any case-control study. However, in this study recall bias is unlikely to explain factors that appear to be protective, which was the case for many of the associations found. A final limitation is that many of the effect sizes were modest.	Talc use on all areas of the body elevated ovarian cancer risk, even after adjustment for potentially important confounding factors. Environmental factors and medical conditions that increased the risk included talc use…. The spectrum of associations provides support for the hypothesis that inflammation may mediate ovarian cancer risk.

	use of talc to the genital area or underwear.			
Mills (2004)	Case Control Study. Population based. Evaluated 256 cases from cancer registries and 1,122 population-based controls from in 22 counties of Central California. Women were queried about their talcum powder use in the genital area, years of use, frequency of use, and total duration of use. Invasive and borderline tumors were studied.	Ever use of perineal talc had an increased risk for ovarian cancer with an odds ratio **1.37 (1.02-1.85).** Increasing frequency of use was associated with increasing risk- women using talc 4-7 times per week had an odds ratio of **1.74 (1.14-2.64)** for ovarian cancer (p=0.015). There was an indication of trend with duration of use up to 4-12 years OR **1.86 (1.16-2.98),** but the number of years beyond that did not increase risk further. A similar relationship was found for cumulative dose (frequency x duration) and risk peaked in second and third quartiles (p=0.051). Risk for women with serous invasive tumors had an odds ratio of **1.77 (1.12-2.81).**	The sample size was relatively small and the response fraction lower than ideal. Recall bias has been implicated…. It has also been suggested that use of talc is habitual versus memorable and not likely to be subject to recall bias. Treatment effect is also a limitation.	This study provides some support for the hypothesis that perineal talc use is associated with an increased risk for epithelial ovarian cancer. The precautionary principal should be invoked, especially given that this is serous form of cancer, usually associated with a poor prognosis, with no current effective screening tool…. Unlike other forma of environmental exposures, talcum powder use is easily avoidable.
Merritt (2008)	Case Control Study. Population based. Evaluated 1,576 women with ovarian cancer and 1,509 population-based controls from Australia. Women provided information on self-administered questionnaires. To determine use of talcum powder in the perineal region, participants were asked if they had ever used powder or talc in the genital area, on underwear,	Ever use of talc in the perineal region was associated with an odds ratio of **1.17 (1.01-1.36).** The increase was strongest for serous with an odds ratio **1.21 (1.03-1.44)** and was also seen for endometrioid with an odds ratio **1.18 (0.81-1.70).** A trend for duration of use greater than 25 years was seen for all cases with an odds ratio of **1.29 (1.04-1.58) p=0.021).**	Low response rate for controls (47%), which could have resulted in selection bias and possibly lead to an over-representation of health subjects among the controls. Additionally, the analysis of the medical conditions was based entirely on self-reported medical history and as a result the accuracy of these reports could not be confirmed, although self-reports of these miscellaneous conditions are	Former studies together with the current findings support the hypothesis that talc particles are transported to the ovaries via unobstructed fallopian tubes. Focusing on talc use, we found that any use of perineal talc was associated with a small but significantly increased risk of ovarian cancer overall and specifically amongst the invasive and LMP serous tumours although no clear dose-response with increasing duration of use was identified. This finding is consistent with results of previous studies.

	or on sanitary pads/diaphragms. They were also asked about age at first use and years of talc use in these areas. Duration of talcum powder use prior to and after surgical sterilization was calculated, and all analyses were limited to the time when the fallopian tubes would have been patent. Use of talc on arms, chest or abdomen was also collected.		unlikely to be influenced greatly by case/control status.	We conclude that on balance chronic inflammation does not play a major role in the development of ovarian cancer.
Moorman (2009)	*Case control. Population based. Investigated 1,114 cases with histopathologically confirmed tumors as part of the North Carolina Ovarian Cancer Study conducted in a 48-county region of North Carolina. Control women were frequency-matched by age and race/ethnicity. Talc exposure was ascertained through in-person interviews and questionnaire conducted by nurses.*	*After adjusting for age there was an increased risk for ovarian cancer with (ever/never) talc use reported for both whites with an odds ratio of 1.04 (0.82 -1.33) and African American of 1.19 (0.68-2.09).*	The North Carolina Ovarian Cancer Study included more African-American women that any other study of ovarian cancer, but the relatively small sample made it difficult to ascertain which association were true associations and which were due to chance findings. Other limitations included the case-control method. The possibility of bias being introduced due to nonparticipation of ovarian cancer cases and controls should be considered.	The relative importance of ovarian cancer risk factor may differ for African-American women but conclusions were limited by the small sample.
Wu (2009)	*Case control. Population based. Evaluated 609 women with newly diagnosed epithelial ovarian cancer and 688 population-based control women residing in Los Angeles county, CA. Talc*	*After adjusting for race, age, education, tubal ligation, family history, menopausal status, use of oral contraceptives, and parity ever perineal use of talc was associated with an increased relative risk of ovarian cancer 1.53 (1.13-2.09). The risk of ovarian cancer*	Confounding, bias.	The role of talc in the development of ovarian cancer has been studied extensively. In a 2006 review by the International Agency for Research on Cancer (IARC), talc was classified as possibly carcinogenic to humans *(i.e.,* Group 2B) on the basis that most of the 20 epidemiological studies on talc

	exposure was determined through a comprehensive questionnaire that used a reference date of 2 years before the date of diagnosis (or date of interview for controls). Subjects were asked if they ever used talc at least once per month for 6 months or more. If the response was positive, they were asked if they had ever used talc in non-perineal areas, perineal areas or on underwear or sanitary pad/diaphragm. Questions on talc use included age at first use, frequency of use (times per month) and years of talc use.	*increased significantly with increasing frequency and duration of talc use; compared to never users risk and was highest among long duration (20 years), frequent (at least daily) talc users with an adjusted relative risk of 2.08 (1.34-3.23). The association between talc use and risk of ovarian cancer was strongest for serous ovarian cancer with a relative risk for any use of 1.70 (1.27-2.28).*		and ovarian cancer show consistently a 30--60% increased risk associated with talc use. However, only about half of the studies examined exposure response relationships and the evidence for this is less consistent. This study adds to small group of studies that have investigated the combination of frequency and duration of talc use and ovarian cancer. Results show a significant trend with increasing number of total applications. The results also suggest that talc use prior to 1976 may be more important. The lack of sufficient information on frequency, duration and calendar period of talc use may have contributed to misclassification of this exposure variable in some previous studies. OK
Rosenblatt (2011)	Case control. Population based. Evaluated a total of 812 women with ovarian cancer identified through a cancer registry and 1,313 controls from the western Washington population. Sources of genital powder were ascertained, including direct perineal application, use on sanitary napkins and diaphragms, and use of deodorant vaginal spray. For powder use on sanitary napkins and use of vaginal deodorant sprays, the	Risk of ovarian cancer with genital powder was associated with an odds ratio **1.27 (0.97-1.66).** The risk for borderline ovarian tumors showed an odds ratio of **1.55 (1.02-2.37)** and for invasive ovarian cancers the odds ratio was **1.27(0.87-1.58).** Use of powder on either sanitary napkins or diaphragms did not increase risk. Use of vaginal deodorant spray showed an odds ratio **1.15 (0.85-1.56).** None of the dose-response or time variables (years of use, lifetime number of applications, age at first use, age at last use, calendar year of first use, time since first year, time since last use) showed evidence of	The validity of all of these studies, including this may be influenced by the level of non-response among cases and controls and by the potential for misclassification (differentials and non-differential) of exposure status.	IARC has designated perineal exposure to talc as a possible carcinogen in women. A modest association of ovarian cancer with this exposure was seen in the study and in some previous ones, bur the association generally has not been consistent with or among studies. Therefore, no stronger adjective than "possible" appears warranted at this time. It is not evident how (or if) additional investigation will be able to resolve the issue of whether perineal exposure to talc predisposes to ovarian malignancy. Further case-control studies will continue to be hindered by

	authors recorded the total number of months or years in which these products were used. For use of perineal powder, the investigators recorded the age began and ended, number of weeks or months of use per year, and average days per week used. Study participants were also asked about the types of powder used, including talcum, baby, cornstarch, deodorant, body/bath, and other or unknown. The authors then calculated the lifetime duration of use, and estimated lifetime number of applications.	increasing relative risk of ovarian cancer with increasing level of exposure to talcum powder products. Similarly, there was no evidence of increased risk for ovarian cancer with increasing dose of powder use on sanitary napkins, or of vaginal deodorant sprays.		the limitations mentioned above. Data from additional cohort studies would be welcome, but without details concerning the composition of the powders used by cohort members – details that many participants may not be able to provide – the results of such studies may similarly be ambiguous in their interpretation. OK
Kurta (2012)	Case Control. Population based. Evaluated 902 cases of women with ovarian cancer and 1,802 controls from resident of Western Pennsylvania, Eastern Ohio, and Western New York State. Perineal talc use was defined as ever using dusting powder or deodorizing spray on the genital or rectal areas, on sanitary napkins, on underwear, or on diaphragms or cervical caps.	Use of perineal talc showed an increased risk for ovarian cancer with an odds ratio **1.40 (1.16–1.69).**	Reliance on self-reported use of study drugs and talc- recall bias.	Concludes that risk of ovarian cancer is significantly associated with talc use. Compared to Caucasians, African Americans had a significantly increased risk of ovarian cancer. The following variables were also significantly associated with ovarian cancer risk: age at menarche, OC use, parity, gravidity, duration of breastfeeding, perineal talc use, and tubal ligation. OK

Wu (2015)	Case Control. Population based. Investigated the associations of risk of ovarian cancer and talcum powder products use and other risk factors. 1,701 cases were identified through the SEER population-based University of Southern California cancer registry. and 2,319 controls were recruited from the cases' neighborhoods using random selection from population lists. In-person interviews were conducted. To determine use of talcum powder, women were asked if they ever used talc at least once per month for 6 months or more. If the response was positive, they were asked whether they had ever used talc in non-perineal areas (feet, arms, chest or back), perineal areas, or on underwear or sanitary pads/diaphragm. Questions on talc use included age at first use, frequency of use (times per month) and years of talc use.	Use of genital talc for one year or more in combined ethnicities was associated with an increased risk for ovarian cancer with an odds ratio **1.46 (1.27-1.69).** Similar relative risks were seen in non-Hispanic white, Hispanic, and African-American women. For 5 years increments of genital talc use, the risk for ovarian cancer increased with an odds ratio of **1.14 (1.09-1.20).**	Small sample sizes for Hispanics and African Americans	Population attributable risk percentages (PAR%s), defined as the percentages of disease in the population that are attributable to a given risk factor (or set of risk factors), were calculated. The risk associations with six well-accepted factors (parity, oral contraceptive use, tubal ligation, endometriosis, family history of ovarian cancer, and talc use) were comparable and significant in Hispanics, AA, and non-Hispanic whites. As expected, each of these six risk factors had statistically significant effects on risk in all three groups.
Cramer (2016)	Case control. Population based. Reported on association between genital talc use and risk of ovarian cancer.	Genital talc use was associated with an increased risk of ovarian cancer with an odds ratio of **1.33 (1.16-1.52).** Reported a significant trend for greater ovarian cancer risk with	Recall bias. There are no external records to validate talc use reported by study participants to assess whether our degree of	Overall, there is an association between genital talc use and EOC and a significant trend with increasing "talc years" of use.

	Evaluated 2,041 cases of ovarian cancer from tumor boards and registries in Eastern Massachusetts and Massachusetts and 2100 controls identified from the sample population as controls. Participants were asked if they "regularly" or "at least monthly" applied powder to the genital or rectal area, sanitary napkins or tampons, underwear, or non-genital areas. Type of powder, age begun, years used, and applications per month were ascertained. Lifetime exposure was estimated by multiplying frequency of applications per month by months used, and talc-years was calculated. Participants were then divided into quartiles according to these variables. Participants were also asked if their partners dusted or sprayed powder to their genital or rectal areas. Condom and diaphragm use were ascertained as potential sources of genital talc exposure.	increasing talc-years of use. > 7,200 apps (equivalent to >20 years of daily use showed an odds ratio **1.49 (1.06-2.10).**	misclassification is reasonable. Whether the association is a result of confounding must be addressed. No evidence of confounding was identified but authors did find several examples of effect modification that have biological relevance: prolactin may be mediator. There are inherent limitations quantifying a dose–response due to a lack of metrics for how much talc is in an "application," how much enters the vagina, and how much reaches the upper genital tract where, presumably, any deleterious effect is mediated. This may account for the failure to identify a dose–response in many papers on talc and ovarian cancer.	Among many epidemiologic variables, no confounders for the association were identified. The association may be stronger in AA women. OK
Schildkraut (2016)	Case control. Population based. Investigated the association between body powder use	Use of genital powder was associated with an odds ratio **1.44 (1.11-1.86).** A dose response was found for duration of use (> 20	Result could have been spurious do to underreporting of genital talc and sample	Study showed that genital powder use was associated with ovarian cancer risk in AA women and are consistent with localized chronic inflammation

	and ovarian cancer in African American women in 11 geographic areas of the U.S. Evaluated 584 case identified through SEER cancer registries or through hospital departments and 745 controls. Controls were randomly selected from the same populations as the cases. Participants were questioned via phone interview whether they had ever regularly used talc, cornstarch, baby, or deodorizing powders. Women were classified as "regular users" if they reported using any of these powders at least monthly for at least 6 months, and "never users" otherwise. Regular users were asked about frequency and duration of use; use on genital areas, underwear, sanitary napkins, or diaphragms; and use on non-genital areas. Lifetime number of applications was estimated as number of applications per month times number of months used. Occupational exposure (yes/no) was ascertained for a subset of participants.	years was associated with an odds ratio of **1.52 (1.11-2.07)** and number of lifetime applications **(P trend 1.14)** and daily use of genital powder showed an odds ratio of **1.71 (1.26-2.33.)** Histological analysis revealed an odds ratio of **1.38 (1.03-1.85**) for serous and genital use of powder and **1.63 (1.04-2.55**) for non-serous.	size may have been too small.	in the ovary due to particulates that travel through a direct transvaginal route. The dose response observed for duration of genital powder use provides further evidence for the relationship between genital powder and overall EOC risk. Data suggest an increased risk for serous and non-serous subtypes with use of genital powder. The results of the current study suggest that the use of body powder is an especially important modifiable risk factor for EOC in AA women.

III. META-ANALYSES AND POOLED STUDIES

AUTHOR	STUDY DESCRIPTION	FINDINGS	REPORTED LIMITATIONS	AUTHORS' DISCUSSION AND CONCLUSIONS
Harlow (1992)	Meta-Analysis of 6 studies with 1106 cases	Statistically significant OR of 1.3 for any perineal talc exposure Daily vs. <daily talc use and talc use >10 years vs. <10 years were associated with greater risk for ovarian cancer.	Cannot rule out the possibility in differential over- or under-reporting of talc exposure in cases and controls	Because the overall association between genital use of talc and ovarian cancer remains weak, it is unlikely that this exposure-disease pathway is the principal one involved in ovarian cancer etiology. The authors concluded that they calculate that by applying these odds ratios to the exposure rate among cases, the proportion of ovarian cancer incidence attributable to this level of talc exposure is about 10%. They further state that given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For that reason, they discouraged the use of talc in genital hygiene, particularly as a daily habit.
Gross & Berg, 1995	OR = 1.27 Pooled 10 studies – 614 cases Supported by J&J	1.27 (95%CI, 1.09-1.48)	Other risk factors were not adjusted for in a consistent manner across studies. Selection bias and differential bias were not addressed specifically in the studies.	The body of knowledge found in the medical literature does not unequivocally support the hypothesis that talc use by women puts them at an increased risk of ovarian cancer. However, the results of the meta-analyses do suggest the possibility of an increased risk of ovarian cancer due to perineal talc use. Further research in this area *is* warranted by these results.
Cramer, 1999	Meta-analysis Pooled 14 studies plus Cramer 1999 Attributable Risk of 10-11% Ruled out recall bias Grant by NCI	1.36 (95%CI, 1.24-1.49)	Recall: Recall bias seems more likely to affect exposures that have occurred over a short term than those that have occurred over a long term. Since average duration of talc	There is a consistent association between talc and ovarian cancer that appears unlikely to be explained by recall or confounding. The dose-response relationship is weak but improved by considering factors such as closure of the

			use exceeded 20 years in both cases and controls in our current study, genital talc exposure may be less likely to be subject to recall bias. Furthermore, if publicity regarding the association correlated with selective recall, one might expect a trend for cases from more recent studies to report higher exposure rates, but the exposure rates reported do not suggest this is the case. It also seems reasonable that selective recall would lead to cases reporting all types of talc exposure more frequently than controls, but our study found that cases did not report a significant excess of talc use in non-genital areas compared to controls. Confounding: Authors found no evidence that genital talc exposure varied by key risk factors for ovarian cancer such as age, parity or OC use and little variability of the association by these and other variables.	female tract, ovulation and exposure prior to pregnancy, and we have outlined a plausible biologic rationale for this association. Authors estimated that avoidance of talc in genital hygiene might reduce the occurrence of a highly lethal form of cancer by at least 10%. Balanced against what are primarily aesthetic reasons for using talc in genital hygiene, the risk benefit decision is not complex. Appropriate warnings should be provided to women about the potential risks of regular use of talc in the genital area.
Huncharek, 2003[77]	Meta-analysis RR = 1.33 16 studies No disclosure regarding industry relationship.	1.33 (95%CI, 1.16-1.45)	The meta-analysis presented shows inconsistencies in the available data.	Despite the finding of a positive association, demonstration of a dose-response relationship is an important criterion for making causal inferences from epidemiological data. If no

[77] Dr. Muscat and Huncharek were consulting with Johnson & Johnson at the time of this publication. In October 2000, Dr. Huncharek solicited finding for an Ovarian Cancer Meta-Analysis from J&J to be performed by he and Dr. Muscat and he provided J&J with "preliminary results" of his analysis in November 2000. Deposition of Susan Nicholson, dated July 26, 2018; Deposition of Linda Loretz, Ph.D., dated October 1, 2018. In November 2000, J&J, through its senior scientist, John Hopkins provided editorial comments to Dr. Huncharek' s preliminary results that would more strongly refute the relationship between asbestos and talc and causation. JNJ 000377405. These 2000 J&J comments were ultimately incorporated into the final Huncharek Meta-Analysis which was submitted in 2002 and published in 2003.This relationship was not disclosed.

			The summary relative risk may be spurious due to bias or uncontrolled confounding.	relationship exists, a causal link between exposure and disease is questionable. Asbestos contamination of talc has been identified in the past but current production methods limit or completely eliminate contamination. In summary, pooling data from the sixteen available observational studies examining the relationship between perineal use of cosmetic talc and the development of invasive epithelial ovarian cane.er failed to show evidence of a causal relationship.
Langseth, 2008	Meta-analysis 20 case-control studies; one cohort (Gertig) No studies below 1.0 RR IARC review Financed by the Cancer Registry of Norway	1.35 (95%CI, 1.26-1.46) Pooled OR = 1.35 (1.26-1.46)	Methodological factors such as recall bias should always be considered in case-control studies. It could have been a problem had there been widespread publicity about the possible association between use of body powder and cancer. The International Agency for Research on Cancer (IARC) working group considers that there has not been widespread public concern about this issue and therefore considers it unlikely that such a bias could explain the consistent findings. Another source of recall bias could result from the fact that	The evidence in favor of an association, a very large number of studies have found that women who used talc experienced excess risks of ovarian cancer; some results were statistically significant and some were not. There was some indication in the cohort study of an increase in serous tumours. The evidence of talc migrating to the ovaries lends credibility to such a possible association. The main epidemiological evidence against the association is the absence of clear exposure-response associations in most studies, as well as the absence of an overall excess risk in the cohort study. On balance, the epidemiological evidence suggests that use of cosmetic talc in the perineal area may be associated with ovarian cancer risk. The mechanism of carcinogenicity may be related to inflammation. High degree of consistency among studies. The carcinogenicity of non-asbestiform talc was assessed by a monograph working

			women with the cancer tend to remember or overreport their use of body powder. The influence of this type of recall bias cannot be ruled out.	group at IARC in 2006. After considering biases and possible confounding factors, the IARC working group concluded that the epidemiological studies provided limited evidence for the carcinogenicity of perineal use of talc-based body powder, and classified this use as possibly carcinogenic to human beings (that is, group 2B). The current body of experimental and epidemiological evidence is insufficient to establish a causal association between perineal use of talc and ovarian cancer risk.
Berge, 2017	Meta-analysis 24 case-control studies and three cohort studies 302,705 women	Summary RR =1.22 (95%CI, 1.13-1.30) Case-control studies = RR 1.26; cohort studies = 1.02 Serous carcinoma RR = 1.24 There was no trend in RR with either duration or frequency of genital talc use.	The heterogeneity of results by study design and the lack of a trend for duration and frequency of use, however, detract from a causal interpretation of this association.	This meta-analysis resulted in a weak but statistically significant association between genital use of talc and ovarian cancer, which appears to be limited to serous carcinoma.
Penninkilampi, 2018	Meta-analysis 24 case-control (13, 421 cases) and three cohort studies (890 cases, 181,860 person-years)	Any perineal talc use was associated with increased risk of ovarian cancer (OR = 1.31; 95% CI = 1.24, 1.39). More than 3600 lifetime applications (OR = 1.42; 95% CI = 1.25, 1.61) were slightly more associated with ovarian cancer than <3600 (OR = 1.32; 95% CI = 1.15, 1.50). An association with ever use of talc was found in case–control studies (OR = 1.35; 95% CI = 1.27, 1.43), but not cohort studies (OR	A limitation of this study is that it pools nonrandomized studies, primarily case–control studies. The retrospective nature of case–control studies introduces the potential for recall bias. In this case, it is entirely possible that patients with ovarian cancer may be more aware of their previous talc use and hence be more likely to report higher past use. It is possible to attempt to overcome this by blinding the participants to the nature of the study, usually by asking spurious questions;	Hence while case–control studies are low-level evidence, they have been preferred in the investigation of the association between talc use and ovarian cancer. They also have the important advantage of not requiring 15 or more years of follow-up, as is necessary for a cohort study to sufficient detect cases of ovarian cancer relative to certain exposures. One potential way to overcome this limitation in future studies is to ensure that talc use is always included in questionnaires of any cohort studies investigating ovarian cancer. It is important not only that talc use be investigated but also the precise location,

		= 1.06; 95% CI = 0.90, 1.25). However, cohort studies found an association between talc use and invasive serous type ovarian cancer (OR = 1.25; 95% CI = 1.01, 1.55).	however, the effectiveness of this approach may be limited. Many of the studies in this review recorded data about talc use as part of a more extensive questionnaire focused on other associations, which may reduce the potential for recall bias. However, since the initiation of lawsuits in 2014, there has been extensive media coverage regarding this association, and the potential for recall bias in case–control studies conducted since then may be exacerbated.	duration, and frequency of use. As it stands, a meta-analysis of observational studies such as the present study provides the highest level of evidence practically feasible for this research question. The results of this review indicate that perineal talc use is associated with a 24%–39% increased risk of ovarian cancer. While the results of case–control studies are prone to recall bias, especially with intense media attention following the commencement of litigation in 2014, the confirmation of an association in cohort studies between perineal talc use and serous invasive ovarian cancer is suggestive of a causal association.
Terry, 2013	Pooled analysis RR = 1.24 (1.15-1.33) 8 population based studies; 8,525 cases and 9,859 controls (2600 exposed cases) Pooled study; authored by OCAC	Any perineal talc use was associated with increased risk of ovarian cancer (OR = 1.31; 95% CI = 1.24, 1.39). More than 3600 lifetime applications (OR = 1.42; 95% CI = 1.25, 1.61) were slightly more associated with ovarian cancer than <3600 (OR = 1.32; 95% CI = 1.15, 1.50). An association with ever use of talc was found in case–control studies (OR = 1.35; 95% CI = 1.27, 1.43), but not cohort studies (OR = 1.06; 95% CI = 0.90, 1.25). However, cohort studies found an association between talc use and invasive serous type ovarian cancer (OR = 1.25; 95% CI = 1.01, 1.55).	Differences in the wording of questions about genital powder use and retrospective nature of the exposure ascertainment. This results in varying levels of misclassification of true exposure. There was missing data, but was not likely to bias results, according to authors	In conclusion, our large pooled analysis of case-control studies shows a small-to-moderate (20–30%) increased risk of ovarian cancer with genital-powder use, most clearly pertaining to non-mucinous epithelial ovarian tumors. More work is needed to understand how genital powders may exert a carcinogenic effect, and which constituents (e.g. talc) may be involved. Since there are few modifiable risk factors for ovarian cancer, avoidance of genital powders may be a possible strategy to reduce ovarian cancer incidence. The biologic plausibility for the observed association between genital-powder use and ovarian cancer risk has been challenged because evidence for dose-response has been inconsistent. The lack of significant dose-response may reflect the difficulty inherent in accurate recollection of specific details of frequency and duration of genital-powder use. Alternatively, the association between genital-powder exposure and ovarian cancer risk may not

				be linear and a modest exposure may be sufficient to increase cancer risk. When unexposed group was included in the analysis there was a clear dose response w/ increased number of applications.
O'Brien, 2020	Data were pooled from 4 large, US-based cohorts: Nurses' Health Study, Nurses' Health Study II, Sister Study, and Women's Health Initiative Observational Study. Ever, long-term (>20 years, and frequent (>1/week) use of powder in the genital area were studied. The primary analysis examined the association between ever use of powder in the genital area and self-reported incident ovarian cancer.	The pooled sample included 252 745 women (median age at baseline, 57 years) with38% self-reporting use of powder in the genital area. Ten percent reported long-term use, and 2 2% reported frequent use. During a median of 11.2 years of follow-up (3.8 million person-years at risk), 2168 women developed ovarian cancer (58 cases/100 000person-years). Ovarian cancer incidence was 61 cases/100 000 person-years among ever users and 55 cases/100 000 person-years among never users (estimated risk difference at age 70 years, 0.09% [95% CI, −0.02% to 0.19%]; estimated HR, 1.08 [95% CI, 0.99 to 1.17]).The estimated HR for frequent vs never use was 1.09 (95% CI, 0.97 to 1.23) and for long-term vs never use, the HR was 1.01 (95% CI, 0.82 to 1.25). Subgroup analyses were conducted for10 variables; the tests for heterogeneity were not statistically significant for any of these comparisons. While the estimated HR for the association between ever use of powder in the	This study has several limitations": 1) the included cohorts varied widely in how they assessed exposure, particularly the duration and frequency of powder use; 2) use of powder in the genital area could not be assess as a time-varying factor, as none of the four studies collected data on use after baseline; 3) specific exposure windows could not be examined, nor could type of powder used or patency status at time of powder use; 4) as with all observational studies, residual confounding is possible; 5) the study may have limited generalizability; 6) confounding by indication is another potential limitation, and it would occur if women with other underlying conditions that were associated with ovarian cancer were also more likely to use powder in the genital area; 7) because tests to confirm patency were not performed, it is possible that not all women categorized as having a patent reproductive	"In this analysis of pooled data from women in 4 cohorts, there was not a statistically significant association between self-reported use of powder in the genital area and incident ovarian cancer. The HR for the association between ever powder use and incident ovarian cancer was 1.08 (95% CI, 0.99 to 1.17) . . . When restricted to women with patent reproductive tracts at baseline, the HR was 1.13 (95% CI, 1.01 to 1.260." . . . "However, the study may have been underpowered to identify a small increase in risk."

		genital area and ovarian cancer risk among women with a patent reproductive tract was 1.13(95% CI, 1.01 to 1.26), the P value for interaction comparing women with vs without patent reproductive tracts was .15.	tract in this analysis had truly patent tubes.	
Davis (2021)	We used data from five studies in the Ovarian Cancer in Women of African Ancestry consortium. Participants included 620 African-American cases, 1,146 African-American controls,2,800 White cases, and 6,735 White controls who answered questions on genital powder use prior to 2014. The association between genital powder use and ovarian cancer risk by race was estimated using logistic regression.	The prevalence of ever genital powder use for cases was 35.8% among African-American women and 29.5% among White women. Ever use of genital powder was associated with higher odds of ovarian cancer among African-American women [OR:1.22;95% confidence interval (CI): 0.97–1.53] and White women (OR: 1.36; 95% CI: 1.19–1.57). In African-American women, the positive association with risk was more pronounced among high-grade serous tumors (OR: 1.31; 95% CI:1.01–1.71) than with all other histotypes (OR:1.05; 95% CI:0.75–1.47). In White women, a significant association was observed irrespective of histotype (OR:1.33; 95% CI:1.12–1.56 and OR: 1.38; 95% CI:1.15–1.66, respectively)."	Limitations of our study must be considered. Recall bias was not a concern for the cases and controls included in our study from the prospective study (WHI). However, for case–control studies, recall bias can be a concern for some exposures. This is particularly true for genital powder use with the advent of talc related lawsuits in 2014.All our analyses excluded interviews from case–control studies after 2014 to address this issue of recall bias. Genital body powder use was self-reported in each of the contributing OCWAA studies. It is possible that there were systematic differences in the way participants remember or report genital body powder and there were differences in the wording of the genital powder questions in the various studies. However, the definition of genital body powder exposure was the same for cases and controls in each of the individual OCWAA studies and we did not observe heterogeneity across studies in the effect estimates, highlighting that the results from our included prospective study (WHI) were not materially different from the four	In conclusion, in this consortium analysis of AA and White women, while the prevalence of ever genital body powder use was higher among AA women in the OCWAA consortium, the association between genital powder use and ovarian cancer risk was similar among AA and White women. Furthermore, there was not a dose-response relationship between frequency or duration of genital powder use and ovarian cancer risk or any significant differences in association by histotype.

			retrospective case–control studies. It is likely that with the exclusion of interviews conducted in 2014 and later, any misclassification would be non-differential with respect to the outcome, resulting in bias toward the null.	
Woolen (2022)	A systematic review and meta-analysis was conducted according to meta-analysis of observational studies in epidemiology guidelines. . . case-control and cohort studies were included if they reported frequent perineal talcum powder use and an adjusted odds ratio or hazard ratio for ovarian cancer.	Initial database searches returned 761unique citations and after review, eleven studies describing 66,876 patients, and 6542 cancers were included (Cohen's κ= 0.88). Publication quality was high (median NOS = 8, range: 4 to 9). Frequent talcum powder use was associated with an elevated risk of ovarian cancer (adjust-ed pooled summary odds ratio 1.47 (95% CI 1.31, 1.65, P<0.0001). There was no evidence of bias and low heterogeneity (I2= 24%, P=0.22). There was no meaningful difference limiting analysis to publications with a NOS quality score of 8 or 9 or limiting studies based on study design.	The primary strength of our study is our focus on frequent users of perineal talcum powder. Among women who report talcum powder use, the most common frequency is dailyuse,13and this is the first systematic review to focus on multiple times per week users. The results were highly consistent and homogenous, and the included studies were of high quality. The work has limitations as well. We constructed our selection criteria prospectively to include studies with multiple times per week and as close to daily talcum powder exposure as possible. However, this meant that cohort and case-control studies that might have frequent-use patients were excluded if the questionnaire did not explicitly capture this information. The definition of talcum powder use varied by frequency and duration between the case-control and cohort studies. Additionally, studies by Cook et al., Mills et al, Rosenblatt et al, and Schildkraut et al.17were unable to differentiate between use of perineal powders and the small subset using cornstarch (estimated at 1.5%). However, the differences in definition and small inclusion of cornstarch	In this analysis of pooled data 10 case-control studies and a single cohort study, the frequent use of perineal talcum powder use is associated with increased risk of ovarian cancer. These results support women avoiding the frequent use of talcum powder in the perineal area. We found frequent use of perineal talcum powder is associated with an increased risk of ovarian cancer, with a pooled adjusted odds ratio of 1.47 (95% CI 1.31, 1.65).

			likely did not affect the results as there was no evidence for statistical heterogeneity in our study. The included studies were adjusted for multiple covariates. The possibility of additional confounders to the studies likely exists.	

APPENDIX A: RESUME

DAVID A. KESSLER

1969-1973	AMHERST COLLEGE, Amherst, Massachusetts Bachelor of Arts, *magna cum laude* (B.A. Independent Scholar, 1973)
1973-1979	HARVARD MEDICAL SCHOOL, Boston, Massachusetts Doctor of Medicine (M.D. 1979)
1975-1977	UNIVERSITY OF CHICAGO LAW SCHOOL, Chicago, Illinois Doctor of Law (J.D., 1978), Harvard Law School, 1977-1978
1984-1986	NEW YORK UNIVERSITY GRADUATE SCHOOL OF BUSINESS ADMINISTRATION (Manhattanville), Purchase, New York Advanced Professional Certificate in Management

EMPLOYMENT

2021-2023	CHIEF SCIENCE OFFICER, COVID-19 RESPONSE OPERATION WARP SPEED, COUNTERMEASURES ACCELERATION GROUP
2003-present	UNIVERSITYOF CALIFORNIA, SAN FRANCISCO Professor of Pediatrics, Epidemiology and Biostatistics
2003-2007	Dean, School of Medicine Vice Chancellor of Medical Affairs
1997-2003	YALE UNIVERSITY SCHOOL OF MEDICINE Dean Professor of Pediatrics, Internal Medicine, and Public Health
1990-1997	UNITED STATES FOOD AND DRUG ADMINISTRATION Commissioner (Appointed by President George H. W. Bush, Reappointed by President William J. Clinton)
1984-1990	THE HOSPITAL OF THE ALBERT EINSTEIN COLLEGE OF MEDICINE Medical Director
1986-1990	COLUMBIA UNIVERSITY Julius Silver Program in Law, Science and Technology Lecturer on Law
1982-1984	MONTEFIORE MEDICAL CENTER Special Assistant to the President
1981-1984	UNITED STATES SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES, Consultant to the Chairman

HONORARY DEGREES

1992	AMHERST COLLEGE, Amherst, Massachusetts Doctor of Science *honoris causa*
1992	GEORGE WASHINGTON UNIVERSITY, Washington, D.C. Doctor of Science *honoris causa*
1993	PHILADELPHIA COLLEGE OF PHARMACY AND SCIENCE, Philadelphia, Pennsylvania, Doctor of Science *honoris causa*
1993	DICKINSON COLLEGE OF LAW, Carlisle, Pennsylvania Doctor of Laws *honoris causa*
1995	ALBANY MEDICAL COLLEGE, Albany, New York Doctor of Science *honoris causa*
1997	NORTHEASTERN UNIVERSITY, Boston, Massachusetts Doctor of Science *honoris causa*
1998	MOUNT SINAI SCHOOL OF MEDICINE, New York, New York Doctor of Humane Letters *honoris causa*
1998	COLGATE UNIVERSITY, Hamilton, New York Doctor of Science *honoris causa*
1998	YALE UNIVERSITY, New Haven, Connecticut Master of Arts *privation*
1999	CONNECTICUT COLLEGE, New London, Connecticut Doctor of Humane Letters *honoris causa*
2001	DICKINSON COLLEGE, Carlisle, Pennsylvania Doctor of Science, *honoris causa*
2001	UNION COLLEGE, Schenectady, New York Doctor of Laws, *honoris causa*
2002	UNIVERSITY OF LOUISVILLE, Louisville, Kentucky Doctor of Public Service, *honoris causa*
2005	STATE UNIVERSITY OF NEW YORK, Syracuse, NY Doctor of Science, *honoris causa*

2012 DREXEL UNIVERSITY, Philadelphia, PA
Doctor of Science, *honoris causa*

2013 CLAREMONT GRADUATE UNIVERSITY, Claremont, CA
Doctor of Science, *honoris causa*

2021 ALBERT EINSTEIN COLLEGE OF MEDICNE

HONORS

NATIONAL ACADEMY OF SCIENCES, Public Welfare Medal, Honorary Member

INSTITUTE OF MEDICINE, Member

AMERICAN SOCIETY OF CLINICAL ONCOLOGY
Distinguished Service Award for Scientific Achievement

AMERICAN ACADEMY OF ARTS AND SCIENCES, Fellow

PHI BETA KAPPA, Amherst College

UNIVERSITY OF CHICAGO LAW REVIEW, Associate Editor

2008 PUBLIC HEALTH HERO AWARD, UC Berkeley

SIGMA XI, The Scientific Research Society of North America

BARNARD COLLEGE Barnard
Medal of Distinction

CASPAR PLATT AWARD, The University of Chicago Law School

HARVARD BLODGETT AWARD IN BIOLOGY, Amherst College

WHITING FOUNDATION GRANT-IN-AID for research at Sloan-Kettering Institute

NATIONAL SCIENCE FOUNDATION FELLOWSHIP (declined)

JOHN WOODRUFF SIMPSON FELLOWSHIP, awarded by Amherst College for the study of medicine

ALVAN T.--VIOLA D. FULLER AMERICAN CANCER SOCIETY JUNIOR RESEARCH FELLOW (declined)

NATIONAL INSTITUTES OF HEALTH TRAINING FELLOWSHIP RECIPIENT Marine Biological Laboratory,

Woods Hole, Massachusetts

PHI DELTA THETA SCHOLARSHIP
DISTINGUISHED PUBLIC SERVICE AWARD
The George Washington University School of Medicine and Health Sciences

UNITED STATES DEPARTMENT OF JUSTICE, CIVIL DIVISION
Special Citation

AMERICAN SOCIETY OF PUBLIC ADMINISTRATION
National Capitol Area Chapter
President's Award for Outstanding Achievement

AMERICAN FEDERATION FOR AIDS RESEARCH (AmFAR)
Sheldon W. Andelson Public Policy Achievement Award

THE WOODROW WILSON AWARD FOR DISTINGUISHED
GOVERNMENT SERVICE Johns Hopkins University

HAL OGDEN AWARD
Association of State and Territorial Directors of Health Promotion and
Public Health Education and the U. S. Centers for Disease Control

NATIONAL ORGANIZATION FOR RARE DISEASES (NORD)
Outstanding Service to the Public Health Award

MARCH OF DIMES
Franklin Delano Roosevelt Leadership Award

CHILDREN'S HOSPITAL NATIONAL MEDICAL CENTER
Children's Research Institute Award of Academic Excellence

AMERICAN HEART ASSOCIATION
National Public Affairs Special Recognition Award for Food Labeling

ISRAEL CANCER RESEARCH FOUNDATION
President's Award

INSTITUTE FOR ADVANCED STUDIES IN IMMUNOLOGY AND AGING
Lifetime Public Service Award

AMERICAN LUNG ASSOCIATION
Special Recognition Award

UNIVERSITY OF CHICAGO ALUMNI ASSOCIATION
Professional Achievement Award (Washington, D.C. Chapter)

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Award for Excellence in Public Service

NATIONAL KIDNEY CANCER ASSOCIATION
Progressive Leadership Award

JOHNS HOPKINS UNIVERSITY SCHOOL OF PUBLIC HEALTH
Dean's Medal

AMERICAN CANCER SOCIETY
Medal of Honor

AMERICAN HEART ASSOCIATION
Meritorious Achievement Award

WORLD HEALTH ORGANIZATION Pan
American World Health Organization World
No Tobacco Day Award

AMERICAN HEART ASSOCIATION
National Public Affairs Special Recognition Award for Tobacco

PROFESSIONAL ACHIEVEMENT CITATION, University of
Chicago Alumni Association

PENNSYLVANIA HOSPITAL Molly
and Sidney N. Zubrow Award

AMERICAN LUNG ASSOCIATION OF CONNECTICUT
Humanitarian Award

AMERICAN COLLEGE OF PREVENTIVE MEDICINE
Special Recognition Award

ASSOCIATION OF AMERICAN MEDICAL COLLEGES AND THE ROBERT WOOD JOHNSON FOUNDATION
David E. Rogers Award for Improving Health and Healthcare of the American People

JACOBS INSTITUTE OF WOMEN'S HEALTH
Excellence in Women's Health Award

NARAL PRO-CHOICE AMERICA
Lifetime Achievement Award

THE ASSOCIATION OF STATE AND TERRITORIAL CHRONIC DISEASE PROGRAM DIRECTORS
Joseph W. Cullen Award for Outstanding Contributions to Chronic Disease Prevention and Control

THE COLLEGE OF WILLIAM & MARY LAW SCHOOL
2005 Benjamin Rush Medal

CALIFORNIA CENTER FOR PUBLIC HEALTH ADVOCACY
David Kessler Award for Extraordinary Contribution to the Public Health

BOOKS FOR A BETTER LIFE AWARD

INTERNSHIP & RESIDENCY

1981-1982	SENIOR ASSISTANT RESIDENT, Department of Pediatrics, The Johns Hopkins Hospital
1980-1981	ASSISTANT RESIDENT, Department of Pediatrics, The Johns Hopkins Hospital
1979-1980	INTERN, Department of Pediatrics, The Johns Hopkins Hospital

ACADEMIC APPOINTMENTS

2003-present	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO Professor of Pediatrics Professor of Epidemiology and Biostatistics
1997-2003	YALE UNIVERSITY Professor of Pediatrics Professor of Internal Medicine Professor of Public Health
1990-1997	ALBERT EINSTEIN COLLEGE OF MEDICINE Department of Pediatrics Department of Epidemiology and Social Medicine Associate Professor of Pediatrics Associate Professor of Epidemiology and Social Medicine
1988-1990	ALBERT EINSTEIN COLLEGE OF MEDICINE Department of Epidemiology and Social Medicine Assistant Professor
1986-1990	COLUMBIA UNIVERSITY SCHOOL OF LAW Julius Silver Program in Law, Science and Technology Lecturer on Law

1982-1990 ALBERT EINSTEIN COLLEGE OF MEDICINE
Department of Pediatrics
Assistant Professor

SPECIAL STUDY

June 1987 JOHNS HOPKINS SCHOOL OF HYGIENE AND PUBLIC HEALTH
Graduate Summer Program in Epidemiology - Pharmacoepidemiology

June 1985 YALE SCHOOL OF ORGANIZATION AND MANAGEMENT
Advanced Management Studies in Health Care Management

1977-1978 HARVARD LAW SCHOOL, Special Student

RESEARCH EXPERIENCE

Summers 1970-1972 SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH
Division of Drug Resistance, New York, New York
Research Asst

Summer 1972 MARINE BIOLOGICAL LABORATORY, Woods Hole, Massachusetts
Physiology course

1974-1975 CHILDREN'S HOSPITAL MEDICAL CENTER
Department of Surgical Research, Boston, Massachusetts
Research Associate

Summer 1976 DEPARTMENT OF HEALTH, EDUCATION and WELFARE
Office of the General Counsel, Chicago, Illinois
Law Clerk

VISITING COMMITTEE

1992-1994 UNIVERSITY OF CHICAGO LAW SCHOOL

UNIVERSITY ACCREDITATION

2008-2012 WESTERN ASSOCIATION OF SCHOOLS AND COLLEGES,
Chair of LLU Accreditation Committee

2013-2015 NORTHWEST COMMISSION ON COLLEGES AND UNIVERSITIES
University of Washington

SPECIAL PROJECTS

1982-1988 THE ROBERT WOOD JOHNSON FOUNDATION
Program for Hospital Initiatives in Long-Term Care,

1989-1990 THE PEW CHARITABLE TRUSTS
THE ROBERT WOOD JOHNSON FOUNDATION
Program to Strengthen Hospital Nursing Co-Director

CORPORATE BOARD AND ADVISORY POSITIONS AND COMMITTEES

2020 ELLODI PHARMACEUTICALS

2011 - 2020 IMMUCOR
Member of Board, Chairman of Compliance Committee

2008 - 2020 TPG Senior Advior

2011 - 2014 APTALIS HOLDINGS
Member of Board, Chairman of Compliance Committee

2009 –2017 TOKAI
Member of Board

2007 GOOGLE HEALTH ADVISORY COUNCIL

2007 REVOLUTION HEALTH GROUP
Medical Advisory Board

2007 PERSEUS LLC
Advisory Board

2003 – 2014 FLEISHMAN HILLARD INTERNATIONAL COMMUNICATIONS
International Advisory Board

2000 - 2003 PERSEUS-SOROS BIOTECHNOLOGY FUND Scientific Advisory Board

ADVISORY COMMITTEES

2007 THE RHODES TRUST, THE RHODES SCHOLARSHIPS
Chair, California Selection Committee

2006	CENTER FOR THE ADVANCED STUDIES ON AGING, UNIVERSITY OF MIAMI External Advisory Group
2005 -2015	BROAD MEDICAL RESEARCH PROGRAM Advisory Board
2005	CLINTON SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES National Advisory Board
2003, 2013	HEINZ AWARDS (HEINZ FAMILY FOUNDATION) Awards Juror
2003	MARCH OF DIMES Chair, Prematurity Campaign in Northern California
2002 - 2004	CENTER ON ALCOHOL MARKETING AND YOUTH AT GEORGETOWN UNIVERSITY Advisory Board
2001 -	UNIVERSITY OF CHICAGO LAW REVIEW Editorial Advisory Board
2000 - 2005	JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION Oversight Committee
2000	GOVERNOR'S BLUE RIBBON COMMISSION ON MENTAL HEALTH, STATE OF CONNECTICUT Honorary Chair
2000	FILM AID INTERNATIONAL, INTERNATIONAL RESCUE COMMITTEE Advisory Board
1999	WORLD HEALTH ORGANIZATION Expert Panel on Tobacco
1997	ADVISORY COMMITTEE ON TOBACCO AND PUBLIC HEALTH (Co-Chairman with C. Everett Koop)
1993	GOVERNMENT UNIVERSITY INDUSTRY ROUNDTABLE National Academy of Sciences
1990	ADVISORY COMMITTEE ON THE FOOD AND DRUG ADMINISTRATION Chairman, Drugs and Biologics Subcommittee
1988 - 1989	NATIONAL ADVISORY COUNCIL ON HEALTH CARE TECHNOLOGY ASSESSMENT, Department of Health and Human Services, Washington, D.C. Chairman, Patient Outcomes Subcommittee

PRIOR FEDERAL COMMITTEE MEMBERSHIPS

WHITE HOUSE COMMISSION ON PRESIDENTIAL SCHOLARS

NATIONAL COUNCIL ON SCIENCE AND TECHNOLOGY
Committee on Health, Safety and Food R&D, Vice Chair

INSTITUTE OF MEDICINE
Forum On Drug Development and Regulation

INSTITUTE OF MEDICINE
AIDS Roundtable

NATIONAL TASK FORCE ON AIDS DRUG DEVELOPMENT

OFFICE OF SCIENCE AND TECHNOLOGY POLICY Federal Coordinating Council for Science, Engineering and Technology Committee on Life Science and Health Biotechnology Research Subcommittee, Member ex officio

BOARDS OF DIRECTORS

Past

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Chairman of Board

DRUG STRATEGIES

AMHERST COLLEGE BOARD OF TRUSTEES

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION

Chairman, Board of Directors

NATIONAL CENTER FOR ADDICTION AND SUBSTANCE ABUSE COLUMBIA UNIVERSITY

INTERNATIONAL PARTNERSHIP FOR MICROBICIDES INDEPENDENT CITIZENS OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

HENRY J. KAISER FAMILY FOUNDATION

DOCTORS OF THE WORLD

YALE-NEW HAVEN HOSPITAL

CONSUMERS UNION

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NEW YORK COUNTY HEALTH SERVICE REVIEW ORGANIZATION

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Beth Israel Hospital

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Newport Beach Public Library and Newport Beach Public Library Foundation

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Princeton University, Woodrow Wilson School

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Law, Medicine, and Ethics, Kenan Ethics Program, Duke University

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Albert Einstein College of Medicine

MARTIN A. CHERKASKY DISTINGUISHED LECTURESHIP
Robert Wagner Graduate School of Public Service New York University

ALPHA OMEGA ALPHA DISTINGUISHED LECTURESHIP
Cornell Medical School--New York Hospital

ST. GEORGE SOCIETY LECTURESHIP
Johns Hopkins Medical School

GOVERNOR WINTHROP ROCKEFELLER DISTINGUISHED LECTURESHIP University of Arkansas Medical School

MOLLY AND SIDNEY N. ZUBROW LECTURE
Pennsylvania Hospital

LEROY HOECK M.D. DISTINGUISHED LECTURESHIP
Children's Hospital National Medical Center

JULES AND JANE HIRSH HEALTH POLICY ADDRESS
George Washington University

JOHN S. LATTA LECTURESHIP
University of Nebraska Medical
School

PAUL K. SMITH MEMORIAL LECTURE
George Washington University

WOLK HEART FOUNDATION LECTURE
Colgate University

HASTINGS LECTURE
Association for the Advancement of Medical Instrumentation
National Heart, Lung and Blood Institute

INSTITUTE OF MEDICINE 25TH DISTINGUISHED LECTURESHIP University of Washington

RALPH CAZORT LECTURESHIP
Meharry Medical School

DAVID M. IFSHIN MEMORIAL LECTURE
Potomac, Maryland

CHARLES C. LEIGHTON MEMORIAL LECTURE
Leonard David Institute of Health Economics
University of Pennsylvania

D. W. HARRINGTON LECTURE State
University of New York At Buffalo School of
Medicine and Biomedical Sciences

SAMUEL RUBIN LECTURE FOR THE ADVANCEMENT OF LIBERTY
Columbia University

LEO S. WEIL MEMORIAL LECTURE
Tulane Medical Center, Touro Infirmary,
and Louisiana State University School of Medicine

THOMAS PARRIN LECTURE
University of Pittsburgh School of Public Health

DAVID PACKARD LECTURE
Uniformed Services University of the Health Sciences

NORMAN E. ZINBERG LECTURE
Harvard Medical School

JOHN H. ERSKINE LECTURE
St. Jude's Children's Research Hospital

MARTIN V. BONVENTRE MEMORIAL LECTURE
The Brooklyn Hospital Center

PURVES LECTURE
Woodbridge Library, Woodbridge, Connecticut

VISITING SCHOLAR LECTURE University of Oklahoma - Board of Regents Oklahoma Scholar Leadership Extension Program

J. ROSWELL GALLAGHER LECTURER
Society of Adolescent Medicine

KATHERINE BOUCOT STURGIS LECTURESHIP
American College of Preventive Medicine

HELMUT SCHUMANN LECTURE
Dartmouth-Hitchcock Medical Center

50TH ANNIVERSARY COMMUNICATION LECTURE
Centers for Disease Control and Prevention

5TH JAMES BORDLEY III MEMORIAL LECTURE
Mary Imogene Bassett Hospital

TURNER LECTURE
University of California

MARIE SHULSKY MEMORIAL LECTURE ON HEALTH AND SOCIAL RESPONSIBILITY
Fifth Avenue Synagogue, New York, New York

GERTRUDE AND G.D. CRAIN, JR. LECTURE SERIES
Medill School of Journalism, Northwestern University

GEORGE ARMSTRONG LECTURE
Ambulatory Pediatric Society

ARCO FORUM OF PUBLIC AFFAIRS
Institute of Politics, John F. Kennedy School of Government
Harvard University

PAUL LEVINGER LECTURE AND PROFESSORSHIP PRO TEM IN THE ECONOMICS OF HEALTH CARE Brown University

ARNOLD J. SCHWARTZ MEMORIAL HEALTH LECTURE
Robert F. Wagner Graduate School of Public Service New York University

RONALD ALTMAN MEMORIAL LECTURE
Festival of Arts, Books and Culture, Cherry Hills, New Jersey

SAMUEL MARTIN, M.D. III MEMORIAL LECTURE Division of General Internal Medicine and Leonard Davis Institute University of Pennsylvania

CARL J. MARTINSON, M.D. MEMORIAL LECTURESHIP ON HEALTH PROMOTION AND DISEASE PREVENTION University of Minnesota

LEONARD SILK MEMORIAL LECTURE Mt.
Desert Island Biological Laboratories

CALDWELL LECTURE
American Roentgen Ray Society

RICHARD H. DENT LECTURE St.
George's School

ROBERT T. WONG DISTINGUISHED PROFESSORSHIP
University of Hawaii, Manoa

NIDA/American Psychiatric Association Obesity Symposium

HARVARD OBESITY COURSE

STANFORD BARIATRIC COURSE

AMERICAN BARIATRIC SOCIETY

RHODES ENDOWED LECTURE

STAFFORD LITTLE LECTURE PUBLIC LECTURES AT PRINCETON

GERALD AND SALLY DENARDO LECTURESHIP, SANTA CLARA UNIVERSITY

ALEX AND LENA CASPER MEMORIAL LECTURE, MIAMI UNIVERSITY

UNIVERSITY OF VERMONT FOOD SYSTEMS LEADERSHIP

GOOGLE LECTURE

GLOBAL STUDIES SYMPOSIUM, WHITMAN COLLEGE
Excellence in Public Service

DONALD DUNPHY LECTURE, MCCONE HOSPITAL, UNIVERSITY OF NORTH CAROLINA

CENTER FOR GLOBAL HEALTH, STANFORD MEDICAL SCHOOL

STANFORD UNIVERSITY: THE ETHICS OF FOOD & THE ENVIRONMENT

STANFORD MEDICAL SCHOOL, DEPARTMENT OF MEDICINE, GRAND ROUNDS

LEGACY WARNER SERIES LECTURE ON IMPACT OF FAMILY AND SMOKING PREVENTION AND CONTROL ACT

LEADING VOICES IN PUBLIC HEALTH, EAST TENNESSEE STATE UNIVERSITY

92ND STREET YMCA PUBLIC LECTURE, NEW YORK

COMMONWEALTH CLUB OF CALIFORNIA

SAN FRANCISCO PUBLIC LIBRARY LECTURE

KANSAS CITY PUBLIC LIBRARY

YALE ROBERT WOOD JOHNSON CLINICAL SCHOLARS PROGRAM

COMMUNITY/PUBLIC SERVICE AWARDS

NATIONAL ASSOCIATION FOR THE ADVANCEMENT OF COLORED PEOPLE
Montgomery County Chapter
Person of the Year

LEAGUE OF WOMEN VOTERS, NEW YORK
Carrie Chapman Catt Award

COMMON CAUSE
Public Service Achievement Award

AMERICAN ACADEMY OF PEDIATRICS
Excellence in Public Service

BUSINESS WEEK
Best in Public Service

GEORGE ORWELL AWARD FOR HONESTY AND CLARITY
IN PUBLIC LANGUAGE
National Conference of Teachers of English

ANTI-DEFAMATION LEAGUE OF B'NAI BRITH
Man of Achievement Five Towns, New York

GOLDEN SLIPPER CLUB OF PHILADELPHIA
Golden Slipper Award

NATIONAL FATHER'S DAY COMMITTEE
Father of the Year Award

UNITED SENIORS HEALTH COOPERATIVE
Seniors Advocate Award

NATIONAL ASSOCIATION OF GOVERNMENT COMMUNICATORS
Communicator of the Year Award

NATIONAL CONSUMERS LEAGUE
Trumpeter Award

THE INTERNATIONAL PLATFORM ASSOCIATION
George Crile Award

AMERICAN LUNG ASSOCIATION of New York
Life and Breath Award in Public Health

CONSUMER FEDERATION OF AMERICA
Philip Hart Public Service Award

CAMPAIGN FOR TOBACCO FREE KIDS
Distinguished Service Award

MEDICAL SOCIETY OF NEW YORK, 1st District Branch
Public Service Award

ONCOLOGY NURSING SOCIETY
Public Service Award

PUBLIC VOICE FOR FOOD & HEALTH POLICY
Special Recognition Award for Advancing the Consumer Interest in Food and Agriculture Policy

ATTENDING PEDIATRICIAN

2003 - 2013	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO MEDICAL CENTER
1997-2003	YALE-NEW HAVEN HOSPITAL
1982-1990	BRONX MUNICIPAL HOSPITAL CENTER
1982-1990	NORTH CENTRAL BRONX HOSPITAL
1982-1990	MONTEFIORE MEDICAL CENTER
1982-1990	HOSPITAL OF THE ALBERT EINSTEIN COLLEGE OF MEDICINE

COMMUNITY ACTIVITIES

SCARSDALE SCHOOL DISTRICT, Scarsdale, New York

1986-1990	Legislative Affairs Advisory Committee 1988-1990 Buildings and Facilities Advisory Committee
1990	SCARSDALE STUDENT TRANSFER EDUCATION PLAN, Board of Trustees

GENERAL INFORMATION

Address:
9 Oxford Street
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Office Phone:
(415)310-8084

Married:
Paulette Kessler
Two children - Elise and Ben

Born:
May 31, 1951

MEDICAL LICENSURE

California
Connecticut (non-active)
Maryland
New York (non-active)

PUBLICATIONS

Kessler, David A., FAST CARBS, SLOW CARBS, Harper (2020)
快碳水、 慢碳水:
Kessler, David A., CAPTURE: UNRAVELING THE MYSTERY OF MENTAL SUFFERING, Harper, April 2016 Paperback : April, 2017
被绑架的心灵
Kessler, David A. THE END OF OVEREATING: TAKING CONTROL OF THE INSATIABLE AMERICAN APPETITE, Rodale, 2009
Translated and Adapted:
過食にさようなら-止まらない食欲をコントロール [単行本]
K0HEЦ 06Ж0CTBЖУ
이 페이지 번역하기
Perché mangianmo troppo (e come fare per smetteria
Laat je niet volvreten: Hoe de voedselindustgrie schade toebrengt ann onze gexondheid
Das Ende des groben Fressens Wie die Nahrungsmittelindustrie Sie zu ubermaBigem Essen berleitet und was Sie dagegen tun konnen
Muszáj annyit enni? Hadüzenet a só, a zsír és a cukor ellen
Also: Romania, Canada, UK, Australia, India
Your Food is Fooling You: How Your Brain is Hijacked by Sugar Fat and Salt (US Young Adult Version)
Hijacked: How Your Brain is Fooled by Food (Canadian Young Adult Version)

Kessler, David A., A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY, Public Affairs (Hardcover 2001) (Paperback 2002)

Edited Books

Eisdorfer, Carl, Kessler, David A., Spector, Abby (eds.), CARING FOR THE ELDERLY: RESHAPING HEALTH POLICY, Johns Hopkins University Press, 1989. Includes chapter by Coombs, C., Eisdorfer, C., Feiden, K., and Kessler, D.A. "Lessons from the Program for Hospital Initiatives in Long-Term Care."

Articles

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Naleid, A.M., Grimm, J.W., Kessler, David A., Sipols, A.J., Aliakbari, S., Bennett, J.L., Wells, J., Figlewicz, D.P., "Deconstructing the Vanilla Milkshake: the Dominant Effect of Sucrose on Self-administration Flavor Mixtures," APPETITE, 50(1):128-38 (January 2008)

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Editorials

Kessler, David A., Myers, Matthew, "Beyond the Tobacco Settlement," NEW ENGLAND JOURNAL OF MEDICINE, 345:535-537 (August 16, 2001) (editorial)

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Published Speeches

Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD AND DRUG LAW JOURNAL, 52:1-5, presented at the Food and Drug Law Institute's 39th Annual Educational Conference, Washington, D.C. (December 10-11, 1996)

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Kessler, David A., "Statement on Nicotine-Containing Cigarettes," TOBACCO CONTROL, 3:148-158 (1994)

Kessler, David A., "Issues in Approving Drugs for AIDS Treatment," REGULATORY AFFAIRS, 6:189-200 (1994), presented at the Institute of Medicine's 25th anniversary lecture series, Seattle, Washington

Kessler, David A., "FDA's Revitalization of Medical Device Review and Regulation," BIOMEDICAL INSTRUMENTATION AND TECHNOLOGY, May/June 1994:220-226, presented at the AAMI/NIH Cardiovascular Science and Technology Conference, Rockville, Maryland (December 10, 1993)

Kessler, David A., "Harmonization," PHARMACEUTICAL ENGINEERING, 14:38-40 (January/February 1994), presented at the Second International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, Orlando, Florida (October 27, 1993)

Kessler, David A. "The Academic/Industry Interface: The Risks of Scientists Becoming Entrepreneurs," HOPKINS MEDICAL NEWS, Fall 1993:58

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Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD DRUG COSMETIC LAW JOURNAL, 48:1-10 (1993), presented at The Food and Drug Law Institute's 35th Annual Educational Conference, Washington, D.C. (December 8, 1992)

Kessler, David A., "Reinvigorating the Food and Drug Administration," FOOD TECHNOLOGY, 46:20 (August 1992), presented at the Annual Meeting of Institute of Food Technologists, New Orleans, LA (June 20-24, 1992)

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Kessler, David A., "Remarks--1991 Annual DIA Meeting," DRUG INFORMATION JOURNAL (October 1991)

Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD DRUG COSMETIC LAW JOURNAL, 46:773-779 (November 1991), presented at the Association of Food and Drug Officials' Annual Conference, Grand Rapids, MI (June 17, 1991)

Kessler, David A., "Restoring the FDA's Preeminence in Regulation of Food," FOOD DRUG COSMETIC LAW JOURNAL (May 1991)

Kessler, David A., "Remarks Upon Taking the Oath of Office," JOURNAL OF THE ASSOCIATION OF FOOD AND DRUG OFFICIALS, 55:7-10 (April 1991)

Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD DRUG COSMETIC LAW JOURNAL, 46:21-26 (January, 1991), presented at the Food and Drug Law Institute's 33rd Annual Educational Conference, Washington, D.C. (December 11, 1990)

APPENDIX B: PRIOR TESTIMONY

Dr. David Kessler testified at trial or deposition as an expert in the following cases over more than the last twelve years through November 15, 2023:

- ***In re Risperdal***, Philadelphia, PA and Texas cases, including No. 2012CCV-61916-1 (Tex. Dist. Ct. filed Oct. 2, 2012 and Pledger and Walker); Wolken JCCP 4775
- ***Wells v. Allergan, Inc.*** No. 12-973 (W.D. Okla. filed Sept. 4, 2012);
- ***Drake v. Allergan***, Case No. 2013 vv00234 (U.S. Dist. Ct. Burlington, Vermont)
- ***In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.***, MDL No. 2187 (S.D.W.V. filed July 15, 2010)
- ***SB v. Ortho-McNeil-Janssen Pharm., Inc. (In re Risperdal Litig.)***, No. 100503629 (Pa. Ct. Com. Pl. filed May 27, 2010)
- ***In re Yaz & Yasmin (Drospirenone) Marketing, Sales Practices & Prods. Lib. Litig.***, MDL No. 2100 (J.P.M.L. filed July 30, 2009)
- ***In re Flonase Antitrust Litigation*** (American Sales Company, Inc. v. Smithkline Beecham Corp.), 08-cv- 3149, United States District Court, Eastern District of Pennsylvania
- ***Pharmathene, Inc. v. Siga Techs., Inc.***, No. 2627 (Del. Ch. filed Dec. 20, 2006)
- ***Commonwealth v. Merck & Co.***, No. 09-1671 (Ky. Cir. Ct. filed Sept. 28, 2009) (and Utah)
- ***State v. Merck & Co.***, No. 05-3700 (E.D. La. filed Aug. 5, 2005)
- ***Commonwealth Care Alliance v. AstraZeneca Pharm. L.P.***, No. SUCV2005-269 (Mass. Super. Ct. filed Jan. 25, 2005)
- ***Smith & Nephew, Inc. v. N.H. Ins. Co.***, No. 04-3027 (W.D. Tenn. filed Dec. 17, 2004)
- ***In re Neurontin Marketing, Sales Practices & Prods. Liab. Litig.,*** MDL No. 1629 (D. Mass. filed June 9, 2004)
- ***Brown v. Am. Brands, Inc.***, No. 711400 (Cal Super. Ct. filed June 10, 1997)
- ***In re: Actos (Pioglitazone) Prods. Lib. Litig.***, No. 11-md-2299 (W. D. La. filed Dec. 29, 2011)
- ***Brown v RJ Reynolds Tobacco Company et al.***, No. 2007 CA 002855 (Fla. Cir. Ct. filed Nov. 28, 2007)
- ***In re Merck & Co., Inc. Sec., Deriv. & "ERISA" Litig.***, MDL No. 1658, No. 05-2367 (D.N.J. filed May 5, 2005)
- ***In re Prograf Antitrust Litigation,*** MDL No. 2242 (U.S. District Court, District of Massachusetts
- ***In re Nexium Antitrust Litigation,*** MDL No. 2419 (U.S. District Court, District of Massachusetts)
- ***Cabana v. Stryker.*** Superior Court of State of California, Los Angeles
- ***In Re: Fosamax Litigation,*** Civil Action No. 282, (Superior Court of New Jersey, Atlantic County) and Case No. 30-2012-00547764 (Superior Court of California, Orange County)
- ***Western Sugar Coop et al v. Archer-Daniels-Midland Co, et al***, No. 11-03473 (U.S. District Court, Central District of California)
- ***H.B., et al. v. Abbott Laboratories***, No. #15-cv-702-NJR-SCW (U.S. District Court, Southern District of Illinois, filed June 26, 2015)
- ***In re New England Compounding Pharmacy, Inc. Products Liability Litigation***,

MDL No. 2419 (U.S. District Court, District of Massachusetts, filed 2/14/13)

- ***In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.***, MDL No. 3:11-md-02244 (U.S. District Court, Northern District of Texas, filed May 24, 2011)
- ***In re: Tropicana Orange Juice Mktg. & Sales Practices Litig.***, MDL No. 2353, No. 2:11-cv-07382 (U.S. District Court, District of New Jersey, filed Aug. 10, 2012)
- ***In re Cipro Cases I and II*****,** Nos. 4154 & 4220 (Cal. Super. Ct., filed Feb. 25, 2002)
- ***Anders v. Medtronic, Inc., et al.,*** No. 1322-CC10219-02 (Mo Cir. Ct.)
- ***Austin v. C.R. Bard, Inc., et al.***, Case No. 15-cv-8373 (Circuit Court of the 17th Judicial Circuit (Div. 7), Broward County, Florida).
- ***In re Bard IVC Filters Products Liability Litigation***, Case No. 2:15-MD- 02641-DGC.
- ***In re: Zoloft Litigation***, JCCP No. 4771 (Superior Court of California, Orange County)
- ***In re: Testosterone Replacement Therapy Product Liability Litigation***, MDL No. 2545 (U.S. District Court, Northern District of Illinois – Eastern Division)
- ***In re: Xarelto Products Liability Litigation***, MDL No. 2592 (U.S. District Court, Eastern District of Louisiana – New Orleans Division); Philadelphia County Court of Common Pleas
- ***In re: Benicar (Olmesartan) Product Liability Litigation***, Civil No. 15-2606 (U.S. District Court, District of New Jersey)
- ***In re: Cook Medical, Inc. IVC Filters Marketing, Sales Practices and Product Liability Litigation***, MDL No. 2570 (U.S. District Court, Southern District of Indiana – Indianapolis Division)
- ***State of Texas, ex rel. v. AstraZeneca LP, et al.***, Case No. D-1-GN-13-003530 (District Court of Travis County, Texas)
- ***Council for Education and Research on Toxics v. Starbucks Corp. et al.***, case number BC435759
- ***In re: Asacol Antitrust Litigation,*** Case No. 1:15-cv-12730-DJC (U.S. District Court for the District of Massachusetts)
- ***United States v. Merck***. ex rel., In re: Merck Mumps Vaccine Antitrust Litigation (U.S. District Court, Eastern District of Pennsylvania)
- ***Blue Cross Blue Shield v GlaxoSmithKline*** (U.S. District Court, Eastern District of Pennsylvania)
- ***Tinsley v. Streich*** (Circuit Court City of Charlottesville, Virginia))
- ***People of the State of California v. Johnson & Johnson, et al.***, Case No. 37-2016-00017229-CU-MC-CTL (Superior Court of the State of California, County of San Diego)
- ***In re: Taxotere (Docetaxel) Products Liability Litigation***, MDL No. 2740 (U.S. District Court, Eastern District of Louisiana)
- ***In re: National Prescription Opiate Litigation*****,** MDL No. 3804 (U.S. District Court, Northern District of Ohio)
- ***The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee v. Momenta Pharmaceuticals, et al.,*** Case No. 3:15-cv-01100 (U.S. District Court, Middle District of Tennessee)
- ***Coordinated Proceeding Essure Product*** JCCP 4887, Superior Ct of California, Alalameda

- ***In re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation***, 2:18-md-2846 (U.S. District Court, Southern District of Ohio)
- ***People of the State of New York v. Opioid Manufacturers, Distributors and Pharmacies*** *Supreme Court of the State of New York, County of Suffolk*
- ***In re: Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litigation***, Case No. 1:18-md-02819 (U.S. District Court, Eastern District of New York)
- ***Hamilton v. Novartis, et. al.***, Case No. 37-2013-00070440 (California Superior Court)
- ***Hofferth v. Janssen Pharmaceuticals***, Case No. 3:17-01560 (U.S. District Court, D. South Carolina, Columbia Division)

Dr. David Kessler provided sworn expert statements in the following cases:

- ***DePuy ASR Hip System Cases***, No. CJC-10-4649 (Cal. Super. Ct. filed Dec. 22, 2010)
- ***Cordero v. Endoscopy Ctr. of S. Nev. LLC (In the Matter of Endoscopy Ctr. & Associated Businesses)***, No. 08-A-558091-C (Nev. Dist. Ct. filed Feb. 28, 2008)
- ***Jenkins et. al. v. Medtronic, Inc. et al.***, Case No. 2:13cv02985 (U.S. District Court, Western District of Tennessee)
- ***People of the State of California v. Purdue Pharma L.P., et al.***, Case No. 30-2014-00725287-CU-BT-CXC (Superior Court of the State of California, County of Orange)
- ***N.C.minor v. Hain Celestial Group et al.*** Superior Court for the State of California, County of Los Angeles Case No. 21STCV22822

Hourly rate: $1,250/hr

APPENDIX C: MATERIALS CONSIDERED

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21 CFR 178.3297

21 CFR 182.2437

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30(b)(6) Deposition and Exhibits of Joshua Muscat taken on 9.25.18

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30(b)(6) Deposition and Exhibits of Margaret Gurowitz taken on 7.12.18

30(b)(6) Deposition and Exhibits of Mark Pollack taken on 8.29.18

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Hopkins 13
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Hopkins 14
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